Exhibit A

EFiled: Aug 18 2022 11:42PM EDT
Transaction ID 67947542
Case No. N22C-08-173 VLM

IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

Barbara Allison; Martha Adkins; Greg Barber; Domenic Bernabei; Leroy Brackett; Dreama Brant; Anna Braswell; Sandy Brewer; Ronald Coleman; Leodis Conner; Judy Craft; Jeffery Curtis; Linda Di Maria; Cordelia Dickens; Dennis Dubuque; Phillip Dugan; Ronnie Ellison; Tommie Franklin; Joan Fusco; Mary Gallant; Joseph Garcia; Sharon Gilbertson; Cosmo Giusti; Richard Godbout; Tracy Greer; Amber Hamilton - Roberts; Marilynne Harrison; James Henderson; Lillian Henry; Theresa Hodgdon; Teresa Hutcheson; Richard Jarer; Michael Johnson; Pearlie Johnson; Mark Kelly; Mildred Kelly; Russel Krause; Joseph Landrum; Cheryl Langer; Ronnie Lewis; Leon Lindquist, Jr.; James Logan; James Madore; Manuel Madrid; Karen Maestas; Marie Magarelli; Scott Maziarz; Jimmy McCarley; Dirk Monger; Arlene Moore; Robert Neal; Nadine Oglesby; Michael Paige; Elvin Parker; Charles Parrott; Dewey Patterson; Bobby Pearl; Douglas Perritt; Bruce Pollard; Angela Raskell; Harriett Rideeoutte; Kerry Rivera; Victoria Robbins; Wendy Robinson; Yvonne Roper; Wilbert Roundtree; Daniel Rusher; John Ryder; Kerry Schlei; Kornelia Schreiter; Ray Sellers, Jr.; Boyce Sharpe; William Shelly; Janet Sheppard; Glenn Skenadore; Damon Smith; Gloria Smith; Terry Smith; Billy Spearman; Margie Stam; Christine Thomas; Jerald Thompson; Emily Use; Johnny Vollers; Dawn Wagster; Al Williams; Glen Wilson; Jeffrey Wonser; Cindy Yapp; Robert Yates,

Plaintiffs,

v.

GlaxoSmithKline, LLC; Pfizer, Inc.; Boehringer Ingelheim Pharmaceuticals, Inc.; Boehringer Ingelheim USA Corporation; Sanofi-Aventis U.S. LLC; Sanofi U.S. Services,

COMPLAINT

C.A. No.:

JURY TRIAL DEMANDED

Inc.; and Patheon Manufacturing Services LLC.

Defendants.

ORIGINAL COMPLAINT

COMES NOW, above-captioned Plaintiffs, by and through undersigned counsel, and file this, Original Complaint and demand for Jury Trial against the Defendants named herein and allege as follows:

INTRODUCTION

1. This is a personal injury action for damages relating to Defendants' design, manufacture, sale, marketing, advertising, promotion, testing, labeling, packaging, handling, distribution, transportation, and storage of ranitidine-containing drugs including the brand name, Zantac, and its various generic forms ("Ranitidine-Containing Drugs," unless specifically identified).

2. Plaintiffs bring this action for personal injuries suffered as a result of ingesting the defective and unreasonably dangerous Ranitidine-Containing Drugs and developing various cancers and Plaintiffs' sequelae as a result of this ingestion.

3. Zantac is the branded name for ranitidine, a "blockbuster" drug that was sold as a safe and effective antacid. But ranitidine transforms over time and under particular conditions into high levels of N-Nitrosodimethylamine ("NDMA"), a carcinogen that is as potent as it is dangerous. After almost four decades and billions of dollars of sales, ranitidine consumption has caused scores of consumers to develop cancer.

4. As more particularly set forth herein, the Ranitidine-Containing Drugs Plaintiffs ingested are defective, dangerous to human health, unfit and unsuitable to be advertised, marketed, and sold in the United States, were designed, and manufactured improperly, and lacked proper warnings of the dangers associated with their use.

5. NDMA is a potent carcinogen. Discovered as a biproduct in manufacturing rocket fuel in the early 1900s, today, its only use is to induce tumors in animals as part of laboratory experiments. Its only function is to cause cancer. It has no business being in a human body.

6. Zantac, the popular antacid medication that was used by millions of people every day, naturally decays into NDMA during regular transport and storage, and rapidly converts into NDMA after being digested by the human body. The U.S. Food and Drug Administration's (hereafter "FDA") allowable daily limit of NDMA is 96 (nanograms) (hereafter "ng") and yet, in a single dose of Zantac, researchers and Defendants have discovered thousands of ngs of NDMA, and there are estimates of hundreds of thousands of ngs being formed in the human body.

7. These recent revelations by independent researchers have caused widespread recalls of Zantac and its generic forms both domestically and internationally, including the domestic recall by the current owner and controller of the Zantac new drug application ("NDA"). On April 1, 2020, the FDA banned all Ranitidine-Containing Drugs sold in the United States.

8. The high levels of NDMA observed in Ranitidine-Containing Drugs is a function of the ranitidine molecule: (1) the way it breaks down in the human digestive

system; and (2) the way it breaks down when exposed to heat and humidity, in particular, during transport and storage.

9. This lawsuit seeks to hold Defendants responsible for defective design, manufacturing, sale, marketing, advertising, promotion, testing, labeling, packaging, handling, distribution, transportation, and storage that caused Plaintiffs' severe injuries.

PARTIES

I. PLAINTIFFS

10. Plaintiff **Barbara Allison** is a resident and citizen of South Carolina.

11. Plaintiff Allison consumed Ranitidine-Containing Drugs. Plaintiff Allison was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

12. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

13. Had any Defendant warned Plaintiff Allison that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Allison would not have taken Ranitidine-Containing Drugs.

14. Plaintiff Allison is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

15. Plaintiff **Martha Adkins** is a resident and citizen of Wisconsin.

16. Plaintiff Adkins consumed Ranitidine-Containing Drugs. Plaintiff Adkins was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

17. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

18. Had any Defendant warned Plaintiff Adkins that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Adkins would not have taken Ranitidine-Containing Drugs.

19. Plaintiff Adkins is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

20. Plaintiff **Greg Barber** is a resident and citizen of South Dakota.

21. Plaintiff Barber consumed Ranitidine-Containing Drugs. Plaintiff Barber was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

22. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

23. Had any Defendant warned Plaintiff Barber that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Barber would not have taken Ranitidine-Containing Drugs.

24. Plaintiff Barber is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

25. Plaintiff **Domenic Bernabei** is a resident and citizen of Massachusetts.

26. Plaintiff Bernabei consumed Ranitidine-Containing Drugs. Plaintiff Bernabei was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

27. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

28. Had any Defendant warned Plaintiff Bernabei that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Bernabei would not have taken Ranitidine-Containing Drugs.

29. Plaintiff Bernabei is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

30. Plaintiff **Leroy Brackett** is a resident and citizen of Mississippi.

31. Plaintiff Brackett consumed Ranitidine-Containing Drugs. Plaintiff Brackett was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

32. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

33. Had any Defendant warned Plaintiff Brackett that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Brackett would not have taken Ranitidine-Containing Drugs.

34. Plaintiff Brackett is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

35. Plaintiff **Dreama Brant** is a resident and citizen of South Carolina.

36. Plaintiff Brant consumed Ranitidine-Containing Drugs. Plaintiff Brant was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

37. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

38. Had any Defendant warned Plaintiff Brant that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Brant would not have taken Ranitidine-Containing Drugs.

39. Plaintiff Brant is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

40. Plaintiff **Anna Braswell** is a resident and citizen of Maryland.

41. Plaintiff Braswell consumed Ranitidine-Containing Drugs. Plaintiff Braswell was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

42. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

43. Had any Defendant warned Plaintiff Braswell that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Braswell would not have taken Ranitidine-Containing Drugs.

44. Plaintiff Braswell is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

45. Plaintiff **Sandy Brewer** is a resident and citizen of Rhode Island.

46. Plaintiff Brewer consumed Ranitidine-Containing Drugs. Plaintiff Brewer was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

47. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

48. Had any Defendant warned Plaintiff Brewer that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Brewer would not have taken Ranitidine-Containing Drugs.

49. Plaintiff Brewer is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

50. Plaintiff **Ronald Coleman** is a resident and citizen of Kansas.

51. Plaintiff Coleman consumed Ranitidine-Containing Drugs. Plaintiff Coleman was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

52. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

53. Had any Defendant warned Plaintiff Coleman that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Coleman would not have taken Ranitidine-Containing Drugs.

54. Plaintiff Coleman is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

55. Plaintiff **Leodis Conner** is a resident and citizen of Mississippi.

56. Plaintiff Conner consumed Ranitidine-Containing Drugs. Plaintiff Conner was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

57. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

58. Had any Defendant warned Plaintiff Conner that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Conner would not have taken Ranitidine-Containing Drugs.

59. Plaintiff Conner is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

60. Plaintiff **Judy Craft** is a resident and citizen of South Carolina.

61. Plaintiff Craft consumed Ranitidine-Containing Drugs. Plaintiff Craft was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

62. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

63. Had any Defendant warned Plaintiff Craft that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Craft would not have taken Ranitidine-Containing Drugs.

64. Plaintiff Craft is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

65. Plaintiff **Jeffery Curtis** is a resident and citizen of Mississippi.

66. Plaintiff Curtis consumed Ranitidine-Containing Drugs. Plaintiff Curtis was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

67. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

68. Had any Defendant warned Plaintiff Curtis that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Curtis would not have taken Ranitidine-Containing Drugs.

69. Plaintiff Curtis is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

70. Plaintiff **Linda Di Maria** is a resident and citizen of Wisconsin.

71. Plaintiff Di Maria consumed Ranitidine-Containing Drugs. Plaintiff Di Maria was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

72. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

73. Had any Defendant warned Plaintiff Di Maria that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Di Maria would not have taken Ranitidine-Containing Drugs.

74. Plaintiff Di Maria is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

75. Plaintiff **Cordelia Dickens** is a resident and citizen of Mississippi.

76. Plaintiff Dickens consumed Ranitidine-Containing Drugs. Plaintiff Dickens was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

77. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

78. Had any Defendant warned Plaintiff Dickens that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Dickens would not have taken Ranitidine-Containing Drugs.

79. Plaintiff Dickens is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

80. Plaintiff **Dennis Dubuque** is a resident and citizen of Arkansas.

81. Plaintiff Dubuque consumed Ranitidine-Containing Drugs. Plaintiff Dubuque was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

82. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

83. Had any Defendant warned Plaintiff Dubuque that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Dubuque would not have taken Ranitidine-Containing Drugs.

84. Plaintiff Dubuque is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

85. Plaintiff **Phillip Dugan** is a resident and citizen of Arkansas.

86. Plaintiff Dugan consumed Ranitidine-Containing Drugs. Plaintiff Dugan was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

87. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

88. Had any Defendant warned Plaintiff Dugan that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Dugan would not have taken Ranitidine-Containing Drugs.

89. Plaintiff Dugan is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

90. Plaintiff **Ronnie Ellison** is a resident and citizen of South Carolina.

91. Plaintiff Ellison consumed Ranitidine-Containing Drugs. Plaintiff Ellison was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

92. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

93. Had any Defendant warned Plaintiff Ellison that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Ellison would not have taken Ranitidine-Containing Drugs.

94. Plaintiff Ellison is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

95. Plaintiff **Tommie Franklin** is a resident and citizen of Mississippi.

96. Plaintiff Franklin consumed Ranitidine-Containing Drugs. Plaintiff Franklin was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

97. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

98. Had any Defendant warned Plaintiff Franklin that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Franklin would not have taken Ranitidine-Containing Drugs.

99. Plaintiff Franklin is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

100. Plaintiff **Joan Fusco** is a resident and citizen of New Hampshire.

101. Plaintiff Fusco consumed Ranitidine-Containing Drugs. Plaintiff Fusco was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

102. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

103. Had any Defendant warned Plaintiff Fusco that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Fusco would not have taken Ranitidine-Containing Drugs.

104. Plaintiff Fusco is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

105. Plaintiff **Mary Gallant** is a resident and citizen of Connecticut.

106. Plaintiff Gallant consumed Ranitidine-Containing Drugs. Plaintiff Gallant was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with Colorectal/Intestinal cancer.

107. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

108. Had any Defendant warned Plaintiff Gallant that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Gallant would not have taken Ranitidine-Containing Drugs.

109. Plaintiff Gallant is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

110. Plaintiff **Joseph Garcia** is a resident and citizen of New Mexico.

111. Plaintiff Garcia consumed Ranitidine-Containing Drugs. Plaintiff Garcia was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

112. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

113. Had any Defendant warned Plaintiff Garcia that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Garcia would not have taken Ranitidine-Containing Drugs.

114. Plaintiff Garcia is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

115. Plaintiff **Sharon Gilbertson** is a resident and citizen of Wisconsin.

116. Plaintiff Gilbertson consumed Ranitidine-Containing Drugs. Plaintiff Gilbertson was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

117. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

118. Had any Defendant warned Plaintiff Gilbertson that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Gilbertson would not have taken Ranitidine-Containing Drugs.

119. Plaintiff Gilbertson is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

120. Plaintiff **Cosmo Giusti** is a resident and citizen of Florida.

121. Plaintiff Giusti consumed Ranitidine-Containing Drugs. Plaintiff Giusti was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

122. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

123. Had any Defendant warned Plaintiff Giusti that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Giusti would not have taken Ranitidine-Containing Drugs.

124. Plaintiff Giusti is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

125. Plaintiff **Richard Godbout** is a resident and citizen of Massachusetts.

126. Plaintiff Godbout consumed Ranitidine-Containing Drugs. Plaintiff Godbout was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

127. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

128. Had any Defendant warned Plaintiff Godbout that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Godbout would not have taken Ranitidine-Containing Drugs.

129. Plaintiff Godbout is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

130. Plaintiff **Tracy Greer** is a resident and citizen of Mississippi.

131. Plaintiff Greer consumed Ranitidine-Containing Drugs. Plaintiff Greer was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

132. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

133. Had any Defendant warned Plaintiff Greer that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Greer would not have taken Ranitidine-Containing Drugs.

134. Plaintiff Greer is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

135. Plaintiff **Amber Hamilton - Roberts** is a resident and citizen of Arkansas.

136. Plaintiff Hamilton - Roberts consumed Ranitidine-Containing Drugs. Plaintiff Hamilton - Roberts was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

137. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

138. Had any Defendant warned Plaintiff Hamilton - Roberts that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Hamilton - Roberts would not have taken Ranitidine-Containing Drugs.

139. Plaintiff Hamilton - Roberts is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff

suffered significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

140. Plaintiff **Marilynne Harrison** is a resident and citizen of Wisconsin.

141. Plaintiff Harrison consumed Ranitidine-Containing Drugs. Plaintiff Harrison was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

142. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

143. Had any Defendant warned Plaintiff Harrison that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Harrison would not have taken Ranitidine-Containing Drugs.

144. Plaintiff Harrison is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

145. Plaintiff **James Henderson** is a resident and citizen of South Carolina.

146. Plaintiff Henderson consumed Ranitidine-Containing Drugs. Plaintiff Henderson was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

147. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

148. Had any Defendant warned Plaintiff Henderson that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Henderson would not have taken Ranitidine-Containing Drugs.

149. Plaintiff Henderson is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

150. Plaintiff **Lillian Henry** is a resident and citizen of Michigan.

151. Plaintiff Henry consumed Ranitidine-Containing Drugs. Plaintiff Henry was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

152. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

153. Had any Defendant warned Plaintiff Henry that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Henry would not have taken Ranitidine-Containing Drugs.

154. Plaintiff Henry is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

155. Plaintiff **Theresa Hodgdon** is a resident and citizen of New Hampshire.

156. Plaintiff Hodgdon consumed Ranitidine-Containing Drugs. Plaintiff Hodgdon was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

157. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

158. Had any Defendant warned Plaintiff Hodgdon that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Hodgdon would not have taken Ranitidine-Containing Drugs.

159. Plaintiff Hodgdon is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

160. Plaintiff **Teresa Hutcheson** is a resident and citizen of Michigan.

161. Plaintiff Hutcheson consumed Ranitidine-Containing Drugs. Plaintiff Hutcheson was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

162. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

163. Had any Defendant warned Plaintiff Hutcheson that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Hutcheson would not have taken Ranitidine-Containing Drugs.

164. Plaintiff Hutcheson is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

165. Plaintiff **Richard Jarer** is a resident and citizen of New York.

166. Plaintiff Jarer consumed Ranitidine-Containing Drugs. Plaintiff Jarer was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with Colorectal/Intestinal cancer.

167. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

168. Had any Defendant warned Plaintiff Jarer that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Jarer would not have taken Ranitidine-Containing Drugs.

169. Plaintiff Jarer is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

170. Plaintiff **Michael Johnson** is a resident and citizen of Washington.

171. Plaintiff Johnson consumed Ranitidine-Containing Drugs. Plaintiff Johnson was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

172. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

173. Had any Defendant warned Plaintiff Johnson that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Johnson would not have taken Ranitidine-Containing Drugs.

174. Plaintiff Johnson is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

175. Plaintiff **Pearlie Johnson** is a resident and citizen of South Carolina.

176. Plaintiff Johnson consumed Ranitidine-Containing Drugs. Plaintiff Johnson was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

177. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

178. Had any Defendant warned Plaintiff Johnson that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Johnson would not have taken Ranitidine-Containing Drugs.

179. Plaintiff Johnson is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

180. Plaintiff **Mildred Kelly** is a resident and citizen of Mississippi.

181. Plaintiff Kelly consumed Ranitidine-Containing Drugs. Plaintiff Kelly was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

182. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

183. Had any Defendant warned Plaintiff Kelly that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Kelly would not have taken Ranitidine-Containing Drugs.

184. Plaintiff Kelly is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

185. Plaintiff **Mark Kelly** is a resident and citizen of Mississippi.

186. Plaintiff Kelly consumed Ranitidine-Containing Drugs. Plaintiff Kelly was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

187. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

188. Had any Defendant warned Plaintiff Kelly that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Kelly would not have taken Ranitidine-Containing Drugs.

189. Plaintiff Kelly is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

190. Plaintiff **Russel Krause** is a resident and citizen of Wisconsin.

191. Plaintiff Krause consumed Ranitidine-Containing Drugs. Plaintiff Krause was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

192. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

193. Had any Defendant warned Plaintiff Krause that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Krause would not have taken Ranitidine-Containing Drugs.

194. Plaintiff Krause is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

195. Plaintiff **Joseph Landrum** is a resident and citizen of Mississippi.

196. Plaintiff Landrum consumed Ranitidine-Containing Drugs. Plaintiff Landrum was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

197. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

198. Had any Defendant warned Plaintiff Landrum that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Landrum would not have taken Ranitidine-Containing Drugs.

199. Plaintiff Landrum is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

200. Plaintiff **Cheryl Langer** is a resident and citizen of Wisconsin.

201. Plaintiff Langer consumed Ranitidine-Containing Drugs. Plaintiff Langer was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

202. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

203. Had any Defendant warned Plaintiff Langer that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Langer would not have taken Ranitidine-Containing Drugs.

204. Plaintiff Langer is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

205. Plaintiff **Ronnie Lewis** is a resident and citizen of Mississippi.

206. Plaintiff Lewis consumed Ranitidine-Containing Drugs. Plaintiff Lewis was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

207. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

208. Had any Defendant warned Plaintiff Lewis that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Lewis would not have taken Ranitidine-Containing Drugs.

209. Plaintiff Lewis is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

210. Plaintiff **Leon Lindquist, Jr.** is a resident and citizen of Maine.

211. Plaintiff Lindquist, Jr. consumed Ranitidine-Containing Drugs. Plaintiff Lindquist, Jr. was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

212. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

213. Had any Defendant warned Plaintiff Lindquist, Jr. that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Lindquist, Jr. would not have taken Ranitidine-Containing Drugs.

214. Plaintiff Lindquist, Jr. is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

215. Plaintiff **James Logan** is a resident and citizen of New Mexico.

216. Plaintiff Logan consumed Ranitidine-Containing Drugs. Plaintiff Logan was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

217. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

218. Had any Defendant warned Plaintiff Logan that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Logan would not have taken Ranitidine-Containing Drugs.

219. Plaintiff Logan is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

220. Plaintiff **James Madore** is a resident and citizen of New Mexico.

221. Plaintiff Madore consumed Ranitidine-Containing Drugs. Plaintiff Madore was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

222. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

223. Had any Defendant warned Plaintiff Madore that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Madore would not have taken Ranitidine-Containing Drugs.

224. Plaintiff Madore is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

225. Plaintiff **Manuel Madrid** is a resident and citizen of New Mexico.

226. Plaintiff Madrid consumed Ranitidine-Containing Drugs. Plaintiff Madrid was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

227. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

228. Had any Defendant warned Plaintiff Madrid that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Madrid would not have taken Ranitidine-Containing Drugs.

229. Plaintiff Madrid is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

230. Plaintiff **Karen Maestas** is a resident and citizen of New Mexico.

231. Plaintiff Maestas consumed Ranitidine-Containing Drugs. Plaintiff Maestas was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

232. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

233. Had any Defendant warned Plaintiff Maestas that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Maestas would not have taken Ranitidine-Containing Drugs.

234. Plaintiff Maestas is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

235. Plaintiff **Marie Magarelli** is a resident and citizen of South Carolina.

236. Plaintiff Magarelli consumed Ranitidine-Containing Drugs. Plaintiff Magarelli was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

237. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

238. Had any Defendant warned Plaintiff Magarelli that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Magarelli would not have taken Ranitidine-Containing Drugs.

239. Plaintiff Magarelli is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

240. Plaintiff **Scott Maziarz** is a resident and citizen of Massachusetts.

241. Plaintiff Maziarz consumed Ranitidine-Containing Drugs. Plaintiff Maziarz was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

242. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

243. Had any Defendant warned Plaintiff Maziarz that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Maziarz would not have taken Ranitidine-Containing Drugs.

244. Plaintiff Maziarz is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

245. Plaintiff **Jimmy McCarley** is a resident and citizen of South Carolina.

246. Plaintiff McCarley consumed Ranitidine-Containing Drugs. Plaintiff McCarley was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

247. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

248. Had any Defendant warned Plaintiff McCarley that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff McCarley would not have taken Ranitidine-Containing Drugs.

249. Plaintiff McCarley is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

250. Plaintiff **Dirk Monger** is a resident and citizen of Massachusetts.

251. Plaintiff Monger consumed Ranitidine-Containing Drugs. Plaintiff Monger was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

252. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

253. Had any Defendant warned Plaintiff Monger that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Monger would not have taken Ranitidine-Containing Drugs.

254. Plaintiff Monger is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

255. Plaintiff **Arlene Moore** is a resident and citizen of Mississippi.

256. Plaintiff Moore consumed Ranitidine-Containing Drugs. Plaintiff Moore was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

257. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

258. Had any Defendant warned Plaintiff Moore that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Moore would not have taken Ranitidine-Containing Drugs.

259. Plaintiff Moore is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

260. Plaintiff **Robert Neal** is a resident and citizen of South Carolina.

261. Plaintiff Neal consumed Ranitidine-Containing Drugs. Plaintiff Neal was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

262. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

263. Had any Defendant warned Plaintiff Neal that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Neal would not have taken Ranitidine-Containing Drugs.

264. Plaintiff Neal is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

265. Plaintiff **Nadine Oglesby** is a resident and citizen of Mississippi.

266. Plaintiff Oglesby consumed Ranitidine-Containing Drugs. Plaintiff Oglesby was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

267. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

268. Had any Defendant warned Plaintiff Oglesby that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Oglesby would not have taken Ranitidine-Containing Drugs.

269. Plaintiff Oglesby is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

270. Plaintiff **Michael Paige** is a resident and citizen of Texas.

271. Plaintiff Paige consumed Ranitidine-Containing Drugs. Plaintiff Paige was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

272. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

273. Had any Defendant warned Plaintiff Paige that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Paige would not have taken Ranitidine-Containing Drugs.

274. Plaintiff Paige is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

275. Plaintiff **Elvin Parker** is a resident and citizen of South Carolina.

276. Plaintiff Parker consumed Ranitidine-Containing Drugs. Plaintiff Parker was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

277. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

278. Had any Defendant warned Plaintiff Parker that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Parker would not have taken Ranitidine-Containing Drugs.

279. Plaintiff Parker is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

280. Plaintiff **Charles Parrott** is a resident and citizen of South Carolina.

281. Plaintiff Parrott consumed Ranitidine-Containing Drugs. Plaintiff Parrott was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

282. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

283. Had any Defendant warned Plaintiff Parrott that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Parrott would not have taken Ranitidine-Containing Drugs.

284. Plaintiff Parrott is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

285. Plaintiff **Dewey Patterson** is a resident and citizen of Mississippi.

286. Plaintiff Patterson consumed Ranitidine-Containing Drugs. Plaintiff Patterson was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

287. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

288. Had any Defendant warned Plaintiff Patterson that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Patterson would not have taken Ranitidine-Containing Drugs.

289. Plaintiff Patterson is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

290. Plaintiff **Bobby Pearl** is a resident and citizen of Arkansas.

291. Plaintiff Pearl consumed Ranitidine-Containing Drugs. Plaintiff Pearl was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

292. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

293. Had any Defendant warned Plaintiff Pearl that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Pearl would not have taken Ranitidine-Containing Drugs.

294. Plaintiff Pearl is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

295. Plaintiff **Douglas Perritt** is a resident and citizen of South Carolina.

296. Plaintiff Perritt consumed Ranitidine-Containing Drugs. Plaintiff Perritt was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

297. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

298. Had any Defendant warned Plaintiff Perritt that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Perritt would not have taken Ranitidine-Containing Drugs.

299. Plaintiff Perritt is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

300. Plaintiff **Bruce Pollard** is a resident and citizen of New Hampshire.

301. Plaintiff Pollard consumed Ranitidine-Containing Drugs. Plaintiff Pollard was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

302. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

303. Had any Defendant warned Plaintiff Pollard that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Pollard would not have taken Ranitidine-Containing Drugs.

304. Plaintiff Pollard is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

305. Plaintiff **Angela Raskell** is a resident and citizen of Washington.

306. Plaintiff Raskell consumed Ranitidine-Containing Drugs. Plaintiff Raskell was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

307. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

308. Had any Defendant warned Plaintiff Raskell that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Raskell would not have taken Ranitidine-Containing Drugs.

309. Plaintiff Raskell is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

310. Plaintiff **Harriett Rideeoutte** is a resident and citizen of Missouri.

311. Plaintiff Rideeoutte consumed Ranitidine-Containing Drugs. Plaintiff Rideeoutte was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

312. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

313. Had any Defendant warned Plaintiff Rideeoutte that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Rideeoutte would not have taken Ranitidine-Containing Drugs.

314. Plaintiff Rideeoutte is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

315. Plaintiff **Kerry Rivera** is a resident and citizen of Wisconsin.

316. Plaintiff Rivera consumed Ranitidine-Containing Drugs. Plaintiff Rivera was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

317. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

318. Had any Defendant warned Plaintiff Rivera that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Rivera would not have taken Ranitidine-Containing Drugs.

319. Plaintiff Rivera is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

320. Plaintiff **Victoria Robbins** is a resident and citizen of Wisconsin.

321. Plaintiff Robbins consumed Ranitidine-Containing Drugs. Plaintiff Robbins was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

322. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

323. Had any Defendant warned Plaintiff Robbins that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Robbins would not have taken Ranitidine-Containing Drugs.

324. Plaintiff Robbins is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

325. Plaintiff **Wendy Robinson** is a resident and citizen of South Carolina.

326. Plaintiff Robinson consumed Ranitidine-Containing Drugs. Plaintiff Robinson was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

327. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

328. Had any Defendant warned Plaintiff Robinson that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Robinson would not have taken Ranitidine-Containing Drugs.

329. Plaintiff Robinson is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

330. Plaintiff **Yvonne Roper** is a resident and citizen of South Carolina.

331. Plaintiff Roper consumed Ranitidine-Containing Drugs. Plaintiff Roper was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

332. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

333. Had any Defendant warned Plaintiff Roper that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Roper would not have taken Ranitidine-Containing Drugs.

334. Plaintiff Roper is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

335. Plaintiff **Wilbert Roundtree** is a resident and citizen of Mississippi.

336. Plaintiff Roundtree consumed Ranitidine-Containing Drugs. Plaintiff Roundtree was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

337. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

338. Had any Defendant warned Plaintiff Roundtree that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Roundtree would not have taken Ranitidine-Containing Drugs.

339. Plaintiff Roundtree is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

340. Plaintiff **Daniel Rusher** is a resident and citizen of Arkansas.

341. Plaintiff Rusher consumed Ranitidine-Containing Drugs. Plaintiff Rusher was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

342. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

343. Had any Defendant warned Plaintiff Rusher that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Rusher would not have taken Ranitidine-Containing Drugs.

344. Plaintiff Rusher is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

345. Plaintiff **John Ryder** is a resident and citizen of Rhode Island.

346. Plaintiff Ryder consumed Ranitidine-Containing Drugs. Plaintiff Ryder was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

347. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

348. Had any Defendant warned Plaintiff Ryder that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Ryder would not have taken Ranitidine-Containing Drugs.

349. Plaintiff Ryder is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

350. Plaintiff **Kerry Schlei** is a resident and citizen of Wisconsin.

351. Plaintiff Schlei consumed Ranitidine-Containing Drugs. Plaintiff Schlei was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

352. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

353. Had any Defendant warned Plaintiff Schlei that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Schlei would not have taken Ranitidine-Containing Drugs.

354. Plaintiff Schlei is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

355. Plaintiff **Kornelia Schreiter** is a resident and citizen of South Carolina.

356. Plaintiff Schreiter consumed Ranitidine-Containing Drugs. Plaintiff Schreiter was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

357. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

358. Had any Defendant warned Plaintiff Schreiter that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Schreiter would not have taken Ranitidine-Containing Drugs.

359. Plaintiff Schreiter is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

360. Plaintiff **Ray Sellers, Jr.** is a resident and citizen of Mississippi.

361. Plaintiff Sellers, Jr. consumed Ranitidine-Containing Drugs. Plaintiff Sellers, Jr. was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

362. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

363. Had any Defendant warned Plaintiff Sellers, Jr. that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Sellers, Jr. would not have taken Ranitidine-Containing Drugs.

364. Plaintiff Sellers, Jr. is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

365. Plaintiff **Boyce Sharpe** is a resident and citizen of South Carolina.

366. Plaintiff Sharpe consumed Ranitidine-Containing Drugs. Plaintiff Sharpe was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

367. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

368. Had any Defendant warned Plaintiff Sharpe that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Sharpe would not have taken Ranitidine-Containing Drugs.

369. Plaintiff Sharpe is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

370. Plaintiff **William Shelly** is a resident and citizen of Arkansas.

371. Plaintiff Shelly consumed Ranitidine-Containing Drugs. Plaintiff Shelly was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

372. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

373. Had any Defendant warned Plaintiff Shelly that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Shelly would not have taken Ranitidine-Containing Drugs.

374. Plaintiff Shelly is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

375. Plaintiff **Janet Sheppard** is a resident and citizen of South Carolina.

376. Plaintiff Sheppard consumed Ranitidine-Containing Drugs. Plaintiff Sheppard was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

377. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

378. Had any Defendant warned Plaintiff Sheppard that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Sheppard would not have taken Ranitidine-Containing Drugs.

379. Plaintiff Sheppard is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

380. Plaintiff **Glenn Skenadore** is a resident and citizen of Wisconsin.

381. Plaintiff Skenadore consumed Ranitidine-Containing Drugs. Plaintiff Skenadore was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

382. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

383. Had any Defendant warned Plaintiff Skenadore that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Skenadore would not have taken Ranitidine-Containing Drugs.

384. Plaintiff Skenadore is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

385. Plaintiff **Terry Smith** is a resident and citizen of Mississippi.

386. Plaintiff Smith consumed Ranitidine-Containing Drugs. Plaintiff Smith was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

387. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

388. Had any Defendant warned Plaintiff Smith that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Smith would not have taken Ranitidine-Containing Drugs.

389. Plaintiff Smith is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

390. Plaintiff **Damon Smith** is a resident and citizen of Mississippi.

391. Plaintiff Smith consumed Ranitidine-Containing Drugs. Plaintiff Smith was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

392. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

393. Had any Defendant warned Plaintiff Smith that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Smith would not have taken Ranitidine-Containing Drugs.

394. Plaintiff Smith is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

395. Plaintiff **Gloria Smith** is a resident and citizen of Maryland.

396. Plaintiff Smith consumed Ranitidine-Containing Drugs. Plaintiff Smith was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

397. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

398. Had any Defendant warned Plaintiff Smith that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Smith would not have taken Ranitidine-Containing Drugs.

399. Plaintiff Smith is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

400. Plaintiff **Billy Spearman** is a resident and citizen of Mississippi.

401. Plaintiff Spearman consumed Ranitidine-Containing Drugs. Plaintiff Spearman was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

402. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

403. Had any Defendant warned Plaintiff Spearman that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Spearman would not have taken Ranitidine-Containing Drugs.

404. Plaintiff Spearman is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

405. Plaintiff **Margie Stam** is a resident and citizen of Montana.

406. Plaintiff Stam consumed Ranitidine-Containing Drugs. Plaintiff Stam was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

407. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

408. Had any Defendant warned Plaintiff Stam that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Stam would not have taken Ranitidine-Containing Drugs.

409. Plaintiff Stam is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

410. Plaintiff **Christine Thomas** is a resident and citizen of Arkansas.

411. Plaintiff Thomas consumed Ranitidine-Containing Drugs. Plaintiff Thomas was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

412. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

413. Had any Defendant warned Plaintiff Thomas that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Thomas would not have taken Ranitidine-Containing Drugs.

414. Plaintiff Thomas is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

415. Plaintiff **Jerald Thompson** is a resident and citizen of Montana.

416. Plaintiff Thompson consumed Ranitidine-Containing Drugs. Plaintiff Thompson was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

417. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

418. Had any Defendant warned Plaintiff Thompson that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Thompson would not have taken Ranitidine-Containing Drugs.

419. Plaintiff Thompson is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

420. Plaintiff **Emily Use** is a resident and citizen of Mississippi.

421. Plaintiff Use consumed Ranitidine-Containing Drugs. Plaintiff Use was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

422. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

423. Had any Defendant warned Plaintiff Use that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Use would not have taken Ranitidine-Containing Drugs.

424. Plaintiff Use is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

425. Plaintiff **Johnny Vollers** is a resident and citizen of North Carolina.

426. Plaintiff Vollers consumed Ranitidine-Containing Drugs. Plaintiff Vollers was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with Colorectal/Intestinal cancer.

427. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

428. Had any Defendant warned Plaintiff Vollers that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Vollers would not have taken Ranitidine-Containing Drugs.

429. Plaintiff Vollers is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

430. Plaintiff **Dawn Wagster** is a resident and citizen of Maryland.

431. Plaintiff Wagster consumed Ranitidine-Containing Drugs. Plaintiff Wagster was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

432. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

433. Had any Defendant warned Plaintiff Wagster that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Wagster would not have taken Ranitidine-Containing Drugs.

434. Plaintiff Wagster is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

435. Plaintiff **Al Williams** is a resident and citizen of Mississippi.

436. Plaintiff Williams consumed Ranitidine-Containing Drugs. Plaintiff Williams was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

437. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

438. Had any Defendant warned Plaintiff Williams that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Williams would not have taken Ranitidine-Containing Drugs.

439. Plaintiff Williams is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

440. Plaintiff **Glen Wilson** is a resident and citizen of Wisconsin.

441. Plaintiff Wilson consumed Ranitidine-Containing Drugs. Plaintiff Wilson was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

442. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

443. Had any Defendant warned Plaintiff Wilson that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Wilson would not have taken Ranitidine-Containing Drugs.

444. Plaintiff Wilson is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

445. Plaintiff **Jeffrey Wonser** is a resident and citizen of Washington.

446. Plaintiff Wonser consumed Ranitidine-Containing Drugs. Plaintiff Wonser was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

447. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

448. Had any Defendant warned Plaintiff Wonser that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Wonser would not have taken Ranitidine-Containing Drugs.

449. Plaintiff Wonser is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

450. Plaintiff **Cindy Yapp** is a resident and citizen of Washington.

451. Plaintiff Yapp consumed Ranitidine-Containing Drugs. Plaintiff Yapp was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

452. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

453. Had any Defendant warned Plaintiff Yapp that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Yapp would not have taken Ranitidine-Containing Drugs.

454. Plaintiff Yapp is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

455. Plaintiff **Robert Yates** is a resident and citizen of Maryland.

456. Plaintiff Yates consumed Ranitidine-Containing Drugs. Plaintiff Yates was not aware that ingesting Ranitidine-Containing Drugs led to exposure to NDMA, or that Ranitidine-Containing Drugs caused cancer. As a direct and proximate result of consuming carcinogenic Ranitidine-Containing Drugs, Plaintiff was diagnosed with colorectal/intestinal cancer.

457. Based on scientific evidence, exposure to Ranitidine-Containing Drugs (and the attendant NDMA) can cause cancer in humans, and specifically the type of cancer alleged above.

458. Had any Defendant warned Plaintiff Yates that Ranitidine-Containing Drugs could lead to exposure to NDMA or, in turn, cancer, Plaintiff Yates would not have taken Ranitidine-Containing Drugs.

459. Plaintiff Yates is informed and believes and based thereon alleges that as a direct and proximate result of Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs supplied and distributed by Defendants herein, Plaintiff suffered

significant harm, conscious pain and suffering, physical injury and bodily impairment including, but not limited to cancer, other permanent physical deficits, permanent bodily impairment and other sequelae, lost income, impairment of power to labor and earn money, and will incur past and future medical expenses. Plaintiff's injuries required hospitalizations, in-patient surgeries, medication treatments, and other therapies to address the adverse physical effects and damage caused by Plaintiff's use of and/or exposure to Ranitidine-Containing Drugs.

460. As a direct and proximate result of the wrongful conduct, acts, omissions, fraudulent concealments, fraudulent misrepresentations, and fraudulent business practices by Defendants, Plaintiffs used and/or were exposed to Ranitidine-Containing Drugs and were diagnosed with serious health and emotional injuries including cancer.

461. The product warnings for Ranitidine-Containing Drugs in effect during the time period Plaintiffs used and/or were exposed to Ranitidine-Containing Drugs were vague, incomplete or otherwise inadequate, both substantively and graphically, to alert consumers to the severe health risks associated with Ranitidine-Containing Drugs use and/or exposure.

462. The Defendants did not provide adequate warnings to consumers including Plaintiffs and the general public about the increased risk of serious adverse events that are described herein.

463. Had Plaintiffs been adequately warned of the potential life-threatening side effects of the Defendants' Ranitidine-Containing Drugs, Plaintiffs would not have purchased, used or been exposed to Ranitidine-Containing Drugs.

464. By reason of the foregoing, Plaintiffs developed serious and dangerous side effects including cancer, related sequelae, physical pain and suffering, mental anguish, and loss of enjoyment of life. By reason of the foregoing, Plaintiffs suffered economic losses and special damages including, but not limited to, loss of earning and medical expenses. Plaintiffs' general and special damages are in excess of the jurisdictional limits of the Court.

465. Plaintiffs have reviewed their potential legal claims and causes of action against the Defendants and have intentionally chosen only to pursue claims based on state law. Any reference to any federal agency, regulation, or rule is stated solely as background information and does not raise a federal question. Plaintiffs have chosen to only pursue claims based on state law and are not making any claims which raise federal questions. Accordingly, Plaintiffs contend that Delaware state court jurisdiction and venue is proper.

II. DEFENDANTS

466. Defendants are entities that designed, manufactured, marketed, distributed, labeled, packaged, handled, stored, and/or sold ranitidine.

467. Defendant GlaxoSmithKline, LLC ("GSK"), is a Delaware limited liability company with its principal place of business located at 5 Crescent Drive, Philadelphia, Pennsylvania, 19112 and Five Moore Drive, Research Triangle, North Carolina, 27709. GSK is a citizen of Delaware. GSK is a wholly owned subsidiary of GlaxoSmithKline, plc, which is its sole member. At all relevant times, GSK has conducted business and derived substantial revenue from its designing, manufacturing, advertising,

distributing, selling, and marketing of Zantac within the State of Delaware and each state Plaintiffs reside.

468. GSK, and its predecessors, have controlled the prescription Zantac NDAs since 1983.

469. GlaxoSmithKline, plc[1], is a foreign entity and a citizen of the United Kingdom and is not a citizen of any state in the United States. GlaxoSmithKline, plc is the successor-in-interest to the companies that initially developed, patented, and commercialized the molecule known as ranitidine. Ranitidine was initially developed by Allen & Hanburys Ltd., which was a subsidiary of Glaxo Labs Ltd. Allen & Hanburys Ltd. was awarded Patent No. 4,128,658 by the U.S. Patent and Trademark Office in December 1978, which covered the ranitidine molecule. In 1983, the FDA granted approval to Glaxo Holdings, Ltd. to sell Zantac in the United States. Glaxo Holdings, Ltd. was later absorbed into Glaxo Wellcome, PLC. And then, in 2000, GlaxoSmithKline, plc and GSK were created by the merger of Glaxo Wellcome and SmithKline Beecham. At all relevant times, GlaxoSmithKline, plc has conducted business and derived substantial revenue from its designing, manufacturing, advertising, distributing, selling, and marketing of Zantac within the Delaware and each state Plaintiffs reside.

470. Defendant, Pfizer, Inc. ("Pfizer"), is a Delaware corporation with its principal place of business located at 235 East 42nd Street, New York, New York 10017.

[1] GlaxoSmithKline, plc is not a named defendant. GlaxoSmithKline, plc is discussed for context.

Pfizer is a citizen of Delaware and New York. In 1993, Glaxo Wellcome, plc formed a joint venture with Warner-Lambert, Inc. to develop and obtain OTC approval for Zantac. In 1995, NDA 20-520 Zantac OTC 75 mg tablets were approved. In 1998, NDA 20-745 OTC Zantac 75 mg effervescent tablets were approved. Also, in 1998, Warner-Lambert and Glaxo Wellcome ended their joint venture, with Warner-Lambert retaining control over the OTC NDA for Zantac and the Zantac trademark in the United States and Glaxo Wellcome retaining control over the Zantac trademark internationally.[2] In 2000, Pfizer acquired Warner-Lambert and maintained control over the Zantac OTC NDA until December 2006. At all relevant times, Pfizer has conducted business and derived substantial revenue from its manufacturing, advertising, distributing, selling, and marketing of Zantac within the State of Delaware and each state Plaintiffs reside.

471. Defendant Boehringer Ingelheim Pharmaceuticals, Inc., is a Delaware corporation with its principal place of business located at 900 Ridgebury Road, Ridgefield, Connecticut 06877. Boehringer Ingelheim Pharmaceuticals, Inc. is a citizen of Connecticut, Delaware, and Nevada. Boehringer Ingelheim Pharmaceuticals, Inc. is a subsidiary of the German company Boehringer Ingelheim Corporation. Boehringer Ingelheim Pharmaceuticals, Inc. owned and controlled the NDA for over-the-counter ("OTC") Zantac between December 2006 and January 2017 and manufactured and distributed the drug in the United States during that period. At all relevant times, Boehringer Ingelheim Pharmaceuticals, Inc. has conducted business and derived

[2] *See Warner-Lambert and Glaxo End A Venture on Ulcer Drug Zantac*, WALL STREET JOURNAL (Aug. 4, 1998), available at https://www.wsj.com/articles/SB902188417685803000.

substantial revenue from its manufacturing, advertising, distributing, selling, and marketing of Zantac within the State of Delaware and each state Plaintiffs reside.

472. Defendant Boehringer Ingelheim USA Corporation is a Delaware corporation with its principal place of business located in at 900 Ridgebury Rd., Ridgebury, Connecticut 06877. Boehringer Ingelheim USA Corporation is a citizen of Delaware, Connecticut, and Nevada. At all relevant times, Boehringer Ingelheim USA Corporation has conducted business and derived substantial revenue from its manufacturing, advertising, distributing, selling, and marketing of Zantac within the State of Delaware and each state Plaintiffs reside.

473. Collectively, Defendants Boehringer Ingelheim Pharmaceuticals, Inc. and Defendant Boehringer Ingelheim USA Corporation shall be referred to as "Boehringer".

474. Defendant Sanofi US Services Inc., is a Delaware corporation with its principal place of business located at 55 Corporate Drive, Bridgewater, New Jersey 08807, and is a wholly owned subsidiary of Sanofi S.A. Sanofi is a citizen of Delaware and New Jersey. Sanofi controlled the NDA for OTC Zantac starting in January 2017 through the present and manufactured and distributed the drug in the United States during that period. Sanofi voluntarily recalled all brand name OTC Zantac on October 18, 2019. At all relevant times, Sanofi has conducted business and derived substantial revenue from its manufacturing, advertising, distributing, selling, and marketing of Zantac within the State of Delaware and each state Plaintiffs reside.

475. Defendant Sanofi-Aventis U.S. LLC was and is a Delaware limited liability company with its principal place of business located at 55 Corporate Drive,

Bridgewater, New Jersey 08807. Sanofi-Aventis U.S. LLC is a citizen of Delaware and New Jersey. Sanofi-Aventis US LLC is a wholly owned subsidiary of Sanofi S.A. At all relevant times, Sanofi-Aventis U.S. LLC has conducted business and derived substantial revenue from its manufacturing, advertising, distributing, selling, and marketing of Zantac within the State of Delaware and each state Plaintiffs reside.

476. Collectively, Defendants Sanofi US Services Inc. and Sanofi-Aventis U.S. LLC, shall be referred to as "Sanofi."

477. Defendant Patheon Manufacturing Services LLC is a Delaware limited liability company with its principal place of business located at 5900 Martin Luther King Jr. Hwy, Greenville, North Carolina 27834. Thermo Fisher Scientific, Inc. is the sole member of Defendant Patheon Manufacturing Services LLC. Thermo Fisher Scientific, Inc. is a Delaware corporation with its principal place of business in Massachusetts. Defendant Patheon Manufacturing Services LLC is a citizen of Delaware and Massachusetts. Defendant Patheon Manufacturing Services LLC packaged and manufactured the finished Zantac product for Sanofi. At all relevant times, Patheon Manufacturing Services LLC has conducted business and derived substantial revenue from its manufacturing, advertising, distributing, selling, and marketing of Zantac within the State of Delaware and each state Plaintiffs reside.

478. Throughout the time that Sanofi controlled the OTC Zantac NDAs, Boehringer Ingelheim Promeco, S.A. de C.V. and Patheon Manufacturing Services LLC manufactured the finished drug product.

JURISDICTION AND VENUE

479. This Court has jurisdiction over the subject matter of this action and the parties under the DEL. CONSTIT. art. IV, § 7.

480. The causes of action alleged in this Complaint arise out of or relate to the Defendants' contacts with Delaware. Substantial activities relating to the design, development, marketing, labeling, warnings, promotion and sales of ranitidine-containing products were performed by Defendants in Delaware.

481. This Court possess general personal jurisdiction over each Defendants because they are each incorporated or authorized and licensed to conduct business in Delaware, maintain and carry on systematic and continuous contacts in Delaware, and regularly transact business within Delaware, and are citizens of the State of Delaware.

482. Additionally, Defendants caused tortious injury by acts and omissions in this judicial jurisdiction and caused tortious injury in this jurisdiction by acts and omissions outside this jurisdiction while regularly doing and soliciting business, engaging in a persistent course of conduct, and deriving substantial revenue from goods used or consumed and services rendered in this jurisdiction.

483. Defendants have sufficient minimum contacts with the State of Delaware, such that, "maintenance of the suit does not offend traditional notions of fair play and substantial justice." *International Shoe Co. v. Washington*, 326 U.S. 310 (1945).

484. This Court has personal jurisdiction over Defendants pursuant to, and consistent with, Delaware's long-arm statute, 10 DEL. C. § 3104, and the requirements of Due Process in so far that Defendants, acting through agents or apparent agents,

committed one or more of the following:

a. Defendants transacted, and continue to transact, continuous and systematic business within the State of Delaware and regularly conduct business, receive substantial revenues, and sell products and perform services in the State of Delaware;

b. Defendants caused tortious injury in the State of Delaware by an act or omission in the State of Delaware;

c. Defendants have caused tortious injury to Plaintiffs by engaging in a persistent course of conduct in the State of Delaware and by deriving substantial revenue from services, or things used or consumed in the State of Delaware;

d. Defendants have incorporated under the law of Delaware and registered to conduct business in Delaware, thus expressly consenting to jurisdiction in Delaware;

e. Defendants have an interest in, use or possess real property in the State of Delaware; and

f. Requiring Defendants to litigate this claim in the State of Delaware does not offend traditional notions of fair play and substantial justice and is permitted by the United States Constitution.

485. Venue in this action properly lies in Delaware because all Defendants are citizens of Delaware.

486. This lawsuit is not subject to removal based on the existence of a federal

question. Plaintiffs assert common law and/or statutory claims under state law. These claims do not arise under the Constitution, laws, or treaties of the United States. 28 U.S.C. § 1447(c).

487. This lawsuit is not subject to removal because Plaintiffs assert claims against multiple forum defendants. All Defendants are citizens of Delaware as alleged herein. Defendants are therefore precluded from removing this civil action due to the presence of multiple forum defendants. 28 U.S.C. § 1441(b)(2) ("A civil action . . . may not be removed if any of the parties properly joined and served as defendants is a citizen of the State in which such action is brought.").

488. Additionally, even if removal is effected in contravention of 28 U.S.C. § 1441(b)(2), there is not subject matter jurisdiction within federal court because there is not complete diversity of citizenship between Plaintiffs and Defendants.

489. Plaintiffs seek relief that is within the jurisdictional limits of the Court.

FACTUAL ALLEGATIONS

I. REGULATORY HISTORY OF RANITIDINE-CONTAINING PRODUCTS

490. Defendants marketed and sold Ranitidine-Containing Drugs under the brand name "Zantac" or its generic version by either prescription or OTC. Defendants sold Ranitidine-Containing Drugs in the following forms: injection, syrup, and/or tablets and capsules.

491. Zantac (ranitidine) was originally discovered and developed by scientist

John Bradshaw on behalf of GSK[3] in 1976.

492. The drug belongs to a class of medications called histamine H_2-receptor antagonists (or H_2 blockers), which decrease the amount of acid produced by cells in the lining of the stomach. Other drugs within this class include cimetidine (Tagamet), famotidine (Pepcid), and nizatidine (Tazac).

493. Cimetidine (Tagamet), discovered and developed by Smith, Kline and French[4], was the first H_2 blocker to be developed and is the prototypical histamine H_2 receptor antagonist from which the later members of the class were developed. Indeed, Zantac was specifically developed by GSK in response to the success of cimetidine.

494. Zantac was approved by the FDA, pursuant to the New Drug Application ("NDA") process in 1983 (NDA 18-703) and, quickly, became one of GSK's most successful products, being the first prescription drug in history to reach $1 billion in sales, which in the pharmaceutical industry is referred to as a "Blockbuster."

495. In 1993, GSK entered into a joint venture with Pfizer[5] to develop an OTC version of Zantac. That joint venture led to FDA approval of an OTC version of Zantac

[3] Dr. Bradshaw was working for Glaxo Inc. at the time. Glaxo Inc. later merged with the Wellcome Foundation in 1995 to become Glaxo Wellcome plc. Then, in 2000, Glaxo Wellcome plc merged with Smithkline Beecham plc to form GlaxoSmithKline plc.

[4] Smith, Kline and French later merged with the Beecham Group in 1989 to form SmithKline Beecham plc. and, as discussed above, SmithKline Beecham plc was merged into GSK in 2000.

[5] The joint venture was between Glaxo Wellcome plc and Warner–Lambert, Inc. Warner-Lambert was later acquired by Pfizer, Inc. in 2000. For the purposes of this Complaint, Warner-Lambert will be referred to as Pfizer.

in 1995. Zantac OTC was approved through an NDA process (NDA 20-520).

496. In 1997, GSK's patent on ranitidine expired, and generic Ranitidine-Containing Drugs entered the market. Despite generic entry, however, brand name prescription and OTC Zantac continued to be sold. Although sales of brand-name Zantac declined as a result of generic and alternative products, Ranitidine-Containing Drug sales remained strong over time. As recently as 2018, Zantac was one of the top 10 antacid tablet brands in the United States, with sales of Zantac 150 totaling $128.9 million—a 3.1% increase from the previous year.

497. In 1998, the joint venture between GSK and Pfizer dissolved. As part of the separation, GSK retained the rights to sell all forms of Zantac internationally and prescription Zantac in the U.S., while Pfizer retained the rights to sell OTC Zantac domestically and retained ownership over the Zantac trademark. Under this agreement, GSK retained control and responsibility over the prescription Zantac NDA and Pfizer retained control and responsibility over the OTC Zantac NDA.

498. In October 2000, Pfizer obtained full rights to OTC Zantac in the United States and Canada from GSK pursuant to a divestiture and transfer agreement. As part of this agreement, GSK divested all domestic Zantac OTC assets to Pfizer including all trademark rights and removed the restrictions on Pfizer's ability to seek product line extensions or the approval for higher doses of OTC Zantac. GSK retained the right to exclusive use of the Zantac name for any prescription ranitidine-containing product in the US.

499. In October 2003, Pfizer submitted NDA 21-698 for approval to market

OTC Zantac 150 mg. The FDA approved NDA 21-698 OTC Zantac 150 mg on August 31, 2004.

500. In 2006, Pfizer through a divestiture agreement, transferred all assets pertaining to its Zantac OTC line of products, including the rights to sell and market all formulations of OTC Zantac in the United States and Canada, as well as all intellectual property, research and development, and customer and supply contracts to Boehringer Ingelheim Pharmaceuticals, Inc. As part of this deal, Boehringer obtained control and responsibility over all of the Zantac OTC NDAs.

501. In 2009, GSK ceased marketing prescription Zantac in the U.S. and abandoned the Zantac prescription NDA. Although, according to GSK's recent annual report (2019), GSK claims to have "discontinued making and selling prescription Zantac tablets in 2017 … in the U.S."[6]

502. In 2016, Boehringer sold the rights of OTC Zantac to Sanofi US Services, Inc. As part of this deal, Sanofi obtained control and responsibility over the OTC NDA and currently retains that control and responsibility.

503. To date, the FDA has approved numerous generic manufacturers for the sale of prescription and OTC Ranitidine-Containing Drugs through an Abbreviated New Drug Application ("ANDA") process.

II. RECALLS AND THE FDA'S BAN

504. On September 9, 2019, pharmacy and testing laboratory Valisure LLC and

[6] GlaxoSmithKline, plc, *Annual Report* at 37 (2019), *available at* https://www.gsk.com/media/5894/annual-report.pdf

ValisureRX LLC (collectively, "Valisure") filed a Citizen Petition calling for the recall of all ranitidine-containing products due to exceedingly high levels of NDMA found in ranitidine pills. FDA and European regulators started reviewing the safety of ranitidine with specific focus on the presence of NDMA.[7] This triggered a cascade of recalls by the makers and retailers of Ranitidine-Containing Drugs.

505. On September 13, 2019, the FDA's Director for Drug Evaluation and Research, Dr. Janet Woodcock, issued a statement that some ranitidine medicines may contain NDMA.

506. On September 24, 2019, generic manufacturer Sandoz Inc. voluntarily recalled all of its ranitidine-containing products due to concerns of a "nitrosamine impurity, N-nitrosodimethylamine (NDMA), which was found in the recalled medicine."[8]

507. On September 26, 2019, Walgreens, Walmart, and Rite-Aid and Apotex Corp.— makers of generic OTC ranitidine—voluntarily recalled all ranitidine-containing products and removed the products from the shelves.[9] Apotex issued a statement, noting that "Apotex has learned from the U.S. Food and Drug Administration and other Global regulators that some ranitidine medicines including

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[7] https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine; https://www.ema.europa.eu/en/news/ema-review-ranitidine-medicines-following-detection-ndma.

[8] https://www.fda.gov/news-events/press-announcements/fda-announces-voluntary-recall-sandoz-ranitidine-capsules-following-detection-impurity.

[9] https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine.

brand and generic formulations of ranitidine regardless of the manufacturer, contain a nitrosamine impurity called N-nitrosodimethylamine (NDMA)[.]"[10]

508. On September 28, 2019, CVS Health Corp. stated that it would stop selling Zantac and its own generic ranitidine-containing products out of concern that it might contain a carcinogen.

509. On October 2, 2019, the FDA ordered testing on Zantac and specified a protocol to be used that did not involve the use of heat.[11]

510. On October 8, 2019, GSK voluntarily recalled all Zantac and ranitidine-containing products internationally.[12] As part of the recall, GSK publicly acknowledged that unacceptable levels of NDMA were discovered in Zantac and noted that "GSK is continuing with investigations into the potential source of the NDMA."[13]

511. On October 23, 2019, Dr. Reddy's Laboratories Ltd and Sanofi voluntarily recalled all of their ranitidine-containing products.[14]

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[10] https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/apotex-corp-issues-voluntary-nationwide-recall-ranitidine-tablets-75mg-and-150mg-all-pack-sizes-and.

[11] https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine

[12] https://www.gov.uk/government/news/zantac-mhra-drug-alert-issued-as-glaxosmithkline-recalls-all-unexpired-stock

[13] Justin George Varghese, *GSK recalls popular heartburn drug Zantac globally after cancer scare*, Reuters (Oct. 8, 2019), available at https://www.reuters.com/article/us-gsk-heartburn-zantac/gsk-recalls-popular-heartburn-drug-zantac-globally-after-cancer-scare-idUSKBN1WN1SL.

[14] https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine.

512. On October 28, 2019, Perrigo Company plc, Novitium Pharma LLC, and Lannet Company Inc., voluntarily recalled all their ranitidine-containing products from the market.[15]

513. On November 1, 2019, the FDA announced the results of recent testing, finding "unacceptable levels" of NDMA in ranitidine-containing products, and requested that drug makers begin to voluntarily recall their ranitidine-containing products.[16]

514. Between November 1, 2019 and February 27, 2020, the following ranitidine makers recalled their products from the market, citing NDMA concerns: Aurobindo Pharma USA, Amneal Pharmaceuticals, LLC, American Health Packaging, Golden State Medical Supply, Precision Dose Inc., Glenmark Pharmaceutical Inc., Appco Pharma LLC, and Northwind Pharmaceuticals.[17]

515. On January 2, 2020, research laboratory, Emery Pharma, submitted a Citizen Petition to the FDA, showing that NDMA accumulates in ranitidine at unsafe rates when exposed to heat levels that would occur during transport and storage.

516. Emery's Citizen Petition outlined its substantial concern that Ranitidine is a time- and temperature-sensitive pharmaceutical product that develops a known carcinogen, NDMA, when exposed to heat, a common occurrence during shipping,

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[15] *Id.*

[16] https://www.fda.gov/drugs/drug-safety-and-availability/laboratory-tests-ranitidine.

[17] https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine.

handling, and storage. In addition to warning about this condition, Emery requested agency directives to manufacturers and distributors to ship Ranitidine-Containing Products in temperature-controlled vehicles.

517. In response,[18] on April 1, 2020, the FDA recounted that a recall is an "effective methods [sic.] of removing or correcting defective FDA-regulated products . . . particularly when those products present a danger to health."[19] The FDA sought the voluntary consent of manufacturers to accept the recall "to protect the public health from products that present a risk of injury."[20] The FDA found that the recall of all Ranitidine-Containing Products and public warning of the recall was necessary because the "product being recalled presents a serious health risk."[21] The FDA therefore sent Information Requests to all applicants and pending applicants of Ranitidine-Containing Products "requesting a market withdrawal."[22]

518. The FDA found its stability testing raised concerns that NDMA levels in some ranitidine products stored at room temperature can increase with time to unacceptable levels. Other testing conducted by FDA revealed a correlation between NDMA levels and expiration date. The FDA's testing eroded the agency's confidence

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[18] Letter of Janet Woodcock, Docket No. FDA-2020-P-0042 (April 1, 2020), *available at* https://emerypharma.com/wp-content/uploads/2020/04/FDA-2020-P-0042-CP-Response-4-1-2020.pdf.

[19] *Id., citing* 21 CFR 7.40(a).

[20] *Id.*

[21] *Id.*

[22] *Id.,* fn. 43.

that any ranitidine product could remain stable through its labeled expiration date. Consequently, the FDA was compelled to order the products off the market. The FDA's decision to ban the drug rendered moot Emery's request for temperature-controlled sales conditions.

519. The FDA therefore issued a public statement requesting the immediate removal of all Ranitidine-Containing Products from the market due to the risk to public health.[23] "The agency has determined that the impurity in some ranitidine products increases over time and when stored at higher than room temperatures and may result in consumer exposure to unacceptable levels of this impurity." Based upon its own testing and evaluation, the FDA concluded that "NDMA levels increase in ranitidine even under normal storage conditions and NDMA has been found to increase significantly in samples stored at higher temperatures, including temperatures the product may be exposed to during distribution and handling by consumers."

520. The FDA's reaction to the NDMA crisis involving ranitidine has come under attack. Over 43 different countries and jurisdictions took action to restrict or ban ranitidine-containing products before the FDA took any action.[24] Indeed, despite being notified of the problem by Valisure in June 2019, the FDA left the drug on the market

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[23] Press Release, *FDA Requests Removal of All Ranitidine Products (Zantac) from the Market*, U.S. Food and Drug Administration (April 1, 2020), *available at* https://www.fda.gov/news-events/press-announcements/fda-requests-removal-all-ranitidine-products-zantac-market

[24] Margaret Newkirk and Susan Berfield, *FDA recalls are always voluntary and sometimes haphazard—and the agency doesn't want more authority to protect consumers*, Bloomberg Businessweek (Dec. 3, 2019), *available at* https://www.bloomberg.com/graphics/2019-voluntary-drug-recalls-zantac/.

for nearly an entire year, during which time countless more individuals were exposed to a carcinogen against their will.

521. The FDA's reaction to the NDMA crisis involving ranitidine has come under attack. Over 43 different countries and jurisdictions took action to restrict or ban ranitidine-containing products before the FDA took any action.[25]

III. DANGERS OF NDMA

522. According to the U.S. Environmental Protection Agency ("EPA"), "NDMA is a semivolatile chemical that forms in both industrial and natural processes."[26] It is one of the simplest members of a class of N-nitrosamines, a family of potent carcinogens. The dangers that NDMA poses to human health have long been recognized. A news article published in 1979 noted that "NDMA has caused cancer in nearly every laboratory animal tested so far."[27] NDMA is no longer produced or

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[25] Margaret Newkirk and Susan Berfield, *FDA recalls are always voluntary and sometimes haphazard—and the agency doesn't want more authority to protect consumers*, Bloomberg Businessweek (Dec. 3, 2019), *available at* https://www.bloomberg.com/graphics/2019-voluntary-drug-recalls-zantac/.

[26] United States Environmental Protection Agency, Technical Fact Sheet – N-Nitroso-dimethylamine (NDMA) (Nov. 2017), https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf (last visited Apr. 15, 2020).

[27] Jane Brody, *Bottoms Up: Alcohol in moderation can extend life*, The Globe and Mail (CANADA) (Oct. 11, 1979); *see* Rudy Platiel, *Anger grows as officials unable to trace poison in reserve's water*, The Globe and Mail (CANADA) (Jan. 6, 1990) (reporting that residents of Six Nations Indian Reserve "have been advised not to drink, cook or wash in the water because testing has found high levels of N-nitrosodimethylamine (NDMA), an industrial byproduct chemical that has been linked to cancer"); Kyrtopoulos et al, *DNA adducts in humans after exposure to methylating agents*, 405 MUT. RES. 135 (1998) (noting that "chronic exposure of rats to very low doses of NDMA gives rise predominantly to liver tumors, including tumors of the liver cells (hepatocellular carcinomas), bile ducts, blood vessels and Kupffer cells").

commercially used in the United States, except for research, such as a tumor initiator in animal bioassays. In other words, the only use for NDMA today is to cause cancer in laboratory animals.

523. Both the EPA and the International Agency for Research on Cancer ("IARC") have classified NDMA as a probable human carcinogen.[28]

524. The American Conference of Governmental Industrial Hygienists classifies NDMA as a confirmed animal carcinogen.[29]

525. The U.S. Department of Health and Human Services ("DHHS") states that NDMA is reasonably anticipated to be a human carcinogen.[30] This classification is based upon DHHS's findings that NDMA caused tumors in numerous species of experimental animals, at several different tissue sites, and by several routes of exposure, with tumors occurring primarily in the liver, respiratory tract, kidney, and blood vessels.

526. The FDA considers NDMA a chemical that "could cause cancer" in humans.[31]

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[28] *See* EPA Technical Fact Sheet, *supra*; International Agency for Research on Cancer (IARC) - Summaries & Evaluations, N-NITROSODIMETHYLAMINE (1978), http://www.inchem.org/documents/iarc/vol17/n-nitrosodimethylamine.html (last visited Apr. 15, 2020).

[29] https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf.

[30] *Id.* at 3.

[31] https://www.fda.gov/news-events/press-announcements/statement-alerting-patients-and-health-care-professionals-ndma-found-samples-ranitidine

527. The World Health Organization ("WHO") states that there is "conclusive evidence that NDMA is a potent carcinogen" and that there is "clear evidence of carcinogenicity."[32]

528. As early as 1980, consumer products containing unsafe levels of NDMA and other nitrosamines have been recalled by manufacturers, either voluntarily or at the direction of the FDA.

529. Most recently, beginning in the summer of 2018, there have been recalls of several generic drugs used to treat high blood pressure and heart failure—Valsartan, Losartan, and Irbesartan—because the medications contained nitrosamine impurities that do not meet the FDA's safety standards.

530. The no-observed-adverse-effect level ("NOAEL") is the level of exposure at which there is no biologically or significant increase in the frequency or severity of any adverse effects of the chemical. Due to NDMA's ability to affect DNA at a microscopic level, there is no NOAEL for NDMA. This means any amount of NDMA exposure increases risk.

531. That said, the FDA has set an acceptable daily intake ("ADI") level for NDMA at 96 nanograms. This means, according to the FDA, consumption of 96 nanograms of NDMA a day would increase the risk of developing cancer by 0.001% over the course of a lifetime. That risk increases as the level of NDMA exposure increases. However, any level above 96 nanograms is considered unacceptable. For

[32] World Health Organization, *Guidelines for Drinking Water Quality, N-Nitrosodimethylamine (NDMA)* (3rd ed. 2008), *available at* https://www.who.int/water_sanitation_health/dwq/ chemicals/ndmasummary_2ndadd.pdf.

example, tobacco smoke also contains NDMA. One filtered cigarette contains between 5 to 43 nanograms of NDMA.

532. In mouse studies examining the carcinogenicity of NDMA through oral administration, animals exposed to NDMA developed cancer in the kidney, bladder, liver, and lung. In comparable rat studies, similar cancers were observed in the liver, kidney, pancreas, and lung. In comparable hamster studies, similar cancers were observed in the liver, pancreas, and stomach. In comparable Guinea-pig studies, similar cancers were observed in the liver and lung. In comparable rabbit studies, similar cancers were observed in the liver and lung.

533. In other long-term animal studies in mice and rats utilizing different routes of exposures—inhalation, subcutaneous injection, and intraperitoneal (abdomen injection)—cancer was observed in the lung, liver, kidney, nasal cavity, and stomach.

534. Prior to the agency's ban on Ranitidine-Containing Drugs, the FDA considered the drug as category B for birth defects, meaning it was considered safe to take during pregnancy. However, in animal experiments, for those animals exposed to NDMA during pregnancy, the offspring had elevated rates of cancer in the liver and kidneys.

535. NDMA is, itself, a very small molecule. This allows it to freely pass through all areas of the body, including the blood-brain and placental barrier. This is particularly concerning as ranitidine has been marketed for pregnant women and young children for years.

536. In addition, NDMA breaks down into various derivative molecules that,

themselves, are associated with causing cancer. In animal studies, derivatives of NDMA induced cancer in the stomach and intestine (including colon).

537. Research shows that lower levels of NDMA, *i.e.*, 40 ng, are fully metabolized in the liver, but high doses enter the body's general circulation.

538. Numerous *in vitro* studies confirm that NDMA is a mutagen—causing mutations in human and animal cells.

539. Overall, the animal data demonstrates that NDMA is carcinogenic in all animal species tested: mice, rats, Syrian golden, Chinese and European hamsters, guinea-pigs, rabbits, ducks, mastomys, fish, newts, and frogs.

540. Pursuant to the EPA cancer guidelines, "tumors observed in animals are generally assumed to indicate that an agent may produce tumors in humans."[33]

541. In addition to the overwhelming animal data linking NDMA to cancer, there are numerous human epidemiological studies exploring the effects of dietary exposure to various cancers. And, while these studies (several discussed below) consistently show increased risks of various cancers, the exposure levels considered in these studies are a very small fraction—as little as 1 millionth—the exposures noted in a single Zantac capsule, *i.e.*, 0.191 ng/day (dietary) v. 304,500 ng/day (Zantac).

542. In a 1995 epidemiological case-control study looking at NDMA dietary exposure with 220 cases, researchers observed a statistically significant 700% increased risk of gastric cancer in persons exposed to more than 0.51 ng/day.[34]

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[33] *See* https://www3.epa.gov/airtoxics/cancer_guidelines_final_3-25-05.pdf.

[34] Pobel, *et al.*, *Nitrosamine, nitrate and nitrite in relation to gastric cancer: a case-control study in Marseille, France*, 11 EUROP. J. EPIDEMIOL. 67–73 (1995).

543. In a 1995 epidemiological case-control study looking at NDMA dietary exposure with 746 cases, researchers observed statistically significant elevated rates of gastric cancer in persons exposed to more than 0.191 ng/day.[35]

544. In another 1995 epidemiological case-control study looking at, in part, the effects of dietary consumption on cancer, researchers observed a statistically significant elevated risk of developing aerodigestive cancer after being exposed to NDMA at .179 ng/day.[36]

545. In a 1999 epidemiological cohort study looking at NDMA dietary exposure with 189 cases and a follow up of 24 years, researchers noted that "*N*-nitroso compounds are potent carcinogens" and that dietary exposure to NDMA more than doubled the risk of developing colorectal cancer.[37]

546. In a 2000 epidemiological cohort study looking at occupational exposure of workers in the rubber industry, researchers observed significant increased risks for NDMA exposure for esophagus, oral cavity, pharynx, prostate, and brain cancer.[38]

547. In a 2011 epidemiological cohort study looking at NDMA dietary

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[35] La Vecchia, *et al*., *Nitrosamine intake and gastric cancer risk*, 4 EUROP. J. CANCER. PREV. 469–474 (1995).

[36] Rogers, *et al*., *Consumption of nitrate, nitrite, and nitrosodimethylamine and the risk of upper aerodigestive tract cance*r, 5 CANCER EPIDEMIOL. BIOMARKERS PREV. 29–36 (1995).

[37] Knekt, *et al*., *Risk of Colorectal and Other Gastro-Intestinal Cancers after Exposure to Nitrate, Nitrite and N-nitroso Compounds: A Follow-Up Study*, 80 INT. J. CANCER 852–856 (1999)

[38] Straif, *et al.*, *Exposure to high concentrations of nitrosamines and cancer mortality among a cohort of rubber workers*, 57 OCCUP ENVIRON MED 180–187 (2000).

exposure with 3,268 cases and a follow up of 11.4 years, researchers concluded that "[d]ietary NDMA intake was significantly associated with increased cancer risk in men and women" for all cancers, and that "NDMA was associated with increased risk of gastrointestinal cancers" including rectal cancers.[39]

548. In a 2014 epidemiological case-control study looking at NDMA dietary exposure with 2,481 cases, researchers found a statistically significant elevated association between NDMA exposure and colorectal cancer.[40]

549. In addition to studies demonstrating that NDMA directly causes cancer, research shows that exposure to NDMA (1) can exacerbate existing but dormant cancers (*i.e.*, not malignant), (2) promote otherwise "initiated cancer cells" to develop into cancerous tumors; and (3) reduce the ability of the body to combat cancer. Thus, in addition to NDMA being a direct cause of cancer itself, NDMA can also be a contributing factor to a cancer injury caused by some other source.

550. NDMA is also known to be genotoxic – meaning, it can cause DNA damage in human cells. Indeed, multiple studies demonstrate that NDMA is genotoxic both *in vivo* and *in vitro.* However, recent studies have shown that the ability of NDMA to cause mutations in cells is affected by the presence of enzymes typically found in living humans, suggesting that "humans may be especially sensitive to the

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[39] Loh, *et al*., *N-nitroso compounds and cancer incidence: the European Prospective Investigation into Cancer and Nutrition (EPIC)–Norfolk Study*, 93 AM J CLIN NUTR. 1053–61 (2011).

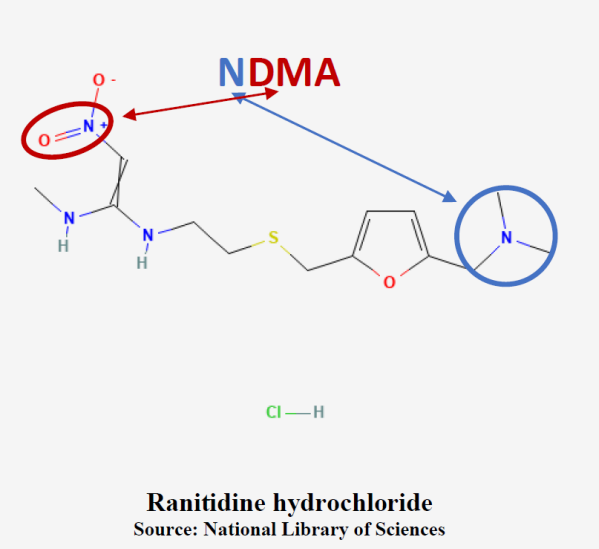
[40] Zhu, *et al*., *Dietary N-nitroso compounds and risk of colorectal cancer: a case-control study in Newfoundland and Labrador and Ontario, Canada*, 111 BR J NUTR. 6, 1109–1117 (2014).

carcinogenicity of NDMA."[41]

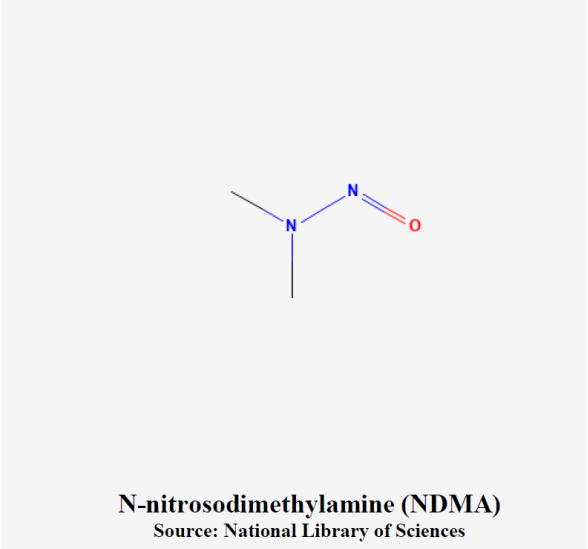
IV. HOW RANITIDINE TRANSFORMS INTO NDMA WITHIN THE HUMAN BODY

551. The NDMA contained in ranitidine-containing products is not caused by any direct contamination. Rather, the ranitidine molecule, itself, contains the constituent molecules to form NDMA. *See* Figure 1.

FIG. 1.



Ranitidine hydrochloride
Source: National Library of Sciences



N-nitrosodimethylamine (NDMA)
Source: National Library of Sciences

Specifically, the O=N (Nitroso) on one side of the ranitidine molecule can combine with the H_3C-N-CH_3 (DMA) on the other side to form NDMA. The NDMA forms out of the ranitidine molecule itself.

552. The formation of NDMA by the reaction of DMA and a nitroso source

[41] World Health Organization, *Guidelines for Drinking Water Quality, N-Nitrosodimethylamine (NDMA)* (3rd ed. 2008), *available at* https://www.who.int/water_sanitation_health/dwq/ chemicals/ndmasummary_2ndadd.pdf.

(such as a nitrite) is well characterized in the scientific literature and has been identified as a concern for contamination of the American water supply.[42] Indeed, in 2003, alarming levels of NDMA in drinking water processed by wastewater treatment plants was specifically linked to the presence of ranitidine.[43]

553. Ranitidine leads to NDMA exposure by: (1) formation of NDMA in the human stomach; (2) formation of NDMA due to an enzymatic reaction throughout the human body; and (3) formation of NDMA due to heat and time.

A. Formation of NDMA in the Environment of the Human Stomach

554. When the ranitidine molecule is exposed to the acidic environment of the stomach, particularly when accompanied by nitrites (a chemical commonly found in heartburn-inducing foods), the Nitroso molecule (0=N) and the DMA molecule (H_3C-N-CH_3) break off and reform as NDMA.

555. In 1981, Dr. Silvio de Flora, an Italian researcher from the University of Genoa, published the results of experiments he conducted on ranitidine in the well-known journal, The Lancet. When ranitidine was exposed to human gastric fluid in combination with nitrites, his experiment showed "toxic and mutagenic effects[.]"[44] Dr. de Flora hypothesized that these mutagenic effects could have been caused by the

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[42] Ogawa, *et al*., *Purification and properties of a new enzyme, NG, NG-dimethylarginine dimethylaminohydrolase, from rat kidney*, 264 J. BIO. CHEM. 17, 10205-10209 (1989).

[43] Mitch, *et al*., *N-Nitrosodimethylamine (NDMA) as a Drinking Water Contaminant: A Review*, 20 ENV. ENG. SCI. 5, 389-404 (2003).

[44] De Flora, *Cimetidine, Ranitidine and Their Mutagenic Nitroso Derivatives*, THE LANCET 993-994 (Oct. 31, 1981).

"formation of more than one nitroso derivative [which includes NDMA] under our experimental conditions." *Id.* Dr. de Flora cautioned that, in the context of ranitidine ingestion, "it would seem prudent to … suggest[] a diet low in nitrates and nitrites, by asking patients not to take these at times close to (or with) meals[.]"[45] *Id.*

556. GSK knew of Dr. de Flora's publication because, two weeks later, GSK responded in The Lancet, claiming that the levels of nitrite needed to induce the production of nitroso derivatives (*i.e.*, NDMA) were not likely to be experienced by people in the real world.[46]

557. In its submission to the FDA, GSK explained that the level of nitrite

> Although N-nitroso-nitrolic acid was a potent mutagen, it is not likely to be formed in the stomach of a patient ingesting ranitidine, as an unrealistically large amount of nitrite needs to be present to form and maintain the nitrosamine. For this reason, and also because ranitidine was not carcinogenic in life-span studies in rodents, the in vitro nitrosation of ranitidine to a mutagenic nitrosamine does not seem to have practical clinical significance.

present would be unrealistic and, thus, these results had no "practical clinical significance"[47]:

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[45] This admonition came two years before the FDA's approved Zantac in 1983. Notwithstanding, in 1998 GSK applied for and obtained an indication for OTC Zantac "[f]or the prevention of meal-induced heartburn at a dose of 75 mg taken 30 to 60 minutes prior to a meal." *See* https://www.accessdata.fda.gov/drugsatfda_docs/nda/98/ 20520s1_Zantac.pdf. So, GSK specifically invited patients to take Zantac shortly before eating heartburn-inducing food.

[46] R. T., Brittain, et al, *Safety of Ranitidine*, THE LANCET (Nov. 14, 1981).

[47] Excerpted from the Summary Basis of Approval submitted to the FDA to obtain approval of Zantac in the early 1980s. This document was obtained through a Freedom of Information Act request to the FDA.

558. Around this same time—before Zantac was approved by the FDA—GSK conducted another study to examine, among other things, how long-term use of ranitidine could affect the levels of nitrite in the human stomach.[48] Remarkably, in the study that was presented to the FDA, GSK admitted that ranitidine use caused the proliferation of bacteria in the human stomach that are known to convert nitrates to nitrites, which leads to elevated levels of nitrite in the stomach environment. GSK acknowledged this could increase the risk of developing NDMA and, in turn, cancer,

> The importance of this finding is not clear. High levels of nitrite could react with certain organic compounds to form nitrosamines, which are known carcinogens. To date, however, neither ranitidine nor cimetidine have been carcinogenic in rodents, so the level of human risk cannot be estimated from animal studies. Ranitidine is recommended only for short-term use and carcinogenic risk, if any, should thus be minimized.

but then dismissed this risk because people were only expected to use ranitidine-containing products for a short-term period:

559. GSK knew—and indeed specifically admitted—that ranitidine could react with nitrite in the human stomach to form NDMA and, at the same time, that long-term use of ranitidine could lead to elevated levels of nitrite in the human stomach.

560. In response to Dr. de Flora's findings, in 1982, GSK conducted a clinical study specifically investigating gastric contents in human patients.[49] The study, in part, specifically measured the levels of N-Nitroso compounds in human gastric fluid. GSK

[48] The results of this study are discussed in the Summary Basis of Approval, obtained from the FDA.

[49] Thomas, *et al*., *Effects of one year's treatment with ranitidine and of truncal vagotomy on gastric contents*, 6 *GUT*. Vol. 28, 726-738 (1987).

indicated that there were no elevated levels, and even published the results of this study five years later, in 1987. The study, however, was rigged. It did not use gold-standard mass spectrometry to test for NDMA, but instead, used a process that could not measure N-nitrosamines efficiently. And worse, in the testing it did do, GSK refused to test gastric samples that contained ranitidine in them out of concern that samples with ranitidine would contain "high concentrations of N-nitroso compounds being recorded." *Id.* So, GSK did not test for NDMA in any gastric fluid that contained ranitidine.

561. In 1983, the same year Zantac obtained approval from the FDA, seven researchers from the University of Genoa published a study discussing ranitidine and its genotoxic effects (ability to harm DNA).[50] The researchers concluded "it appears that reaction of ranitidine with excess sodium nitrite under acid conditions gives rise to a nitroso-derivative (or derivatives) [like NDMA] capable of inducing DNA damage in mammalian cells." *Id.*

562. Then, again in 1983, Dr. de Flora, along with four other researchers, published their complete findings.[51] The results "confirm our preliminary findings on the formation of genotoxic derivatives from nitrite and ranitidine[.]" *Id.* Again, the authors noted that, "the widespread clinical use [of ranitidine] and the possibility of a long-term maintenance therapy suggest the prudent adoption of some simple measures,

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[50] Maura, *et al*., *DNA Damage Induced by Nitrosated Ranitidine in Cultured Mammalian Cells*, 18 TOX. LTTRS. 97-102 (1983).

[51] De Flora, *et al*., *Genotoxicity of nitrosated ranitidine*, 4 CARCINOGENESIS 3, 255-260 (1983).

such as a diet low in nitrates and nitrites or the prescription of these anti-ulcer drugs at a suitable interval from meals." *Id.* This admonition carries weight considering GSK's studies indicate that long-term ranitidine consumption, itself, leads to elevated levels of nitrites in the human gut.

563. The high instability of the ranitidine molecule was elucidated in scientific studies investigating ranitidine as a source of NDMA in drinking water and specific mechanisms for the breakdown of ranitidine were proposed.[52] These studies underscore the instability of the NDMA group on the ranitidine molecule and its ability to form NDMA in the environment of water treatment plants which supply many American cities with water.

564. In 2016, researchers at Stanford University conducted an experiment on healthy volunteers (Stanford Study).[53] They measured the NDMA in urine of healthy individuals over the course of 24 hours, administered one dose of ranitidine, and then measured the NDMA in the urine of the same individuals for another 24 hours. On average, the level of NDMA increased by 400 times, to approximately 47,000 nanograms. The only change during that 24-hour period was the consumption of ranitidine. This study directly demonstrated that unsafe levels of NDMA are formed in the human body as a result of ranitidine ingestion. The scientists further explained that humans do not typically excrete NDMA in their urine, so that the observed 47,000

[52] Le Roux, *et al*., *NDMA Formation by Chloramination of Ranitidine: Kinetics and Mechanism*, 46 *Environ. Sci. Technol.* 20, 11095-11103 (2012).

[53] Zeng, *et al*., *Oral intake of ranitidine increases urinary excretion of N-nitrosodimethylamine*, 37 CARCINOGENESIS 625-634 (2016).

nanograms likely only captured 1/100 of the actual NDMA levels in the human body.

565. These studies did not appreciate the full extent of NDMA formation risk from ranitidine; specifically, the added danger of this drug having not only a labile DMA group but also a readily available nitroso source in its nitrite group on the opposite terminus of the molecule. Recent testing reveals that NDMA levels in ranitidine batches are so high that the nitroso for NDMA likely comes from no other source than the ranitidine molecule itself.

566. Valisure is an online pharmacy that also runs an analytical laboratory that is ISO 17025 accredited by the International Organization for Standardization ("ISO") – an accreditation recognizing the laboratories technical competence for regulatory. Valisure's mission is to help ensure the safety, quality, and consistency of medications and supplements in the market. In response to rising concerns about counterfeit medications, generics, and overseas manufacturing, Valisure developed proprietary analytical technologies that it uses in addition to FDA standard assays to test every batch of every medication it dispenses.

567. In its September 9, 2019 Citizen's Petition to the FDA, Valisure disclosed as part of its testing of Zantac, and other ranitidine-containing products that in every lot tested there were exceedingly high levels of NDMA discovered. Valisure's ISO 17025 accredited laboratory used FDA recommended GC/MS headspace analysis method FY19-005-DPA8 for the determination of NDMA levels. As per the FDA protocol, this

method was validated to a lower limit of detection of 25 ng.[54] The results of Valisure's testing show levels of NDMA well above 2 million ng per 150 mg Zantac tablet, shown below in Table 1.

Table 1 – Ranitidine Samples Tested by Valisure Laboratory Using GC/MS Protocol		
150 mg Tablets or equivalent	Lot #	NDMA per tablet (ng)
Reference Powder*	125619	2,472,531
Zantac, Brand OTC	18M498M	2,511,469
Zantac (mint), Brand OTC	18H546	2,834,798
Wal-Zan, Walgreens	79L800819A	2,444,046
Wal-Zan (mint), Walgreens	8ME2640	2,635,006
Ranitidine, CVS	9BE2773	2,520,311
Zantac (mint), CVS	9AE2864	3,267,968
Ranitidine, Equate	9BE2772	2,479,872
Ranitidine (mint), Equate	8ME2642	2,805,259
Ranitidine, Strides	77024060A	2,951,649

568. Valisure's testing shows, on average, 2,692,291 ng of NDMA in a 150 mg Zantac tablet. Considering the FDA's permissible limit is 96 ng, this would put the level of NDMA at *28,000 times* the legal limit. In terms of smoking, a person would need to

[54] US Food and Drug Administration. (updated 01/25/2019). Combined N-Nitrosodimethlyamine (NDMA) and N-Nitrosodiethylamine (NDEA) Impurity Assay, *FY19-005-DPA-S.*

smoke at least 6,200 cigarettes to achieve the same levels of NDMA found in one 150 mg dose of Zantac.

569. Valisure, however, was concerned that the extremely high levels of NDMA observed in its testing were a product of the modest oven heating parameter of 130 °C in the FDA recommended GC/MS protocol. So, Valisure developed a low temperature GC/MS method that could still detect NDMA but would only subject samples to 37 °C, the average temperature of the human body. This method was validated to a lower limit of detection of 100 ng.

570. Valisure tested ranitidine tablets by themselves and in conditions simulating the human stomach. Industry standard "Simulated Gastric Fluid" ("SGF" 50 mM potassium chloride, 85 mM hydrochloric acid adjusted to pH 1.2 with 1.25 g pepsin per liter) and "Simulated Intestinal Fluid" ("SIF" 50 mM potassium chloride, 50 mM potassium phosphate monobasic adjusted to pH 6.8 with hydrochloric acid and sodium hydroxide) were used alone and in combination with various concentrations of nitrite, which is commonly ingested in foods like processed meats and is elevated in the stomach by antacid drugs. The inclusion of nitrite in gastric fluid testing is commonplace and helps simulate the environment of a human stomach.

571. Indeed, Zantac was specifically advertised to be used when consuming foods containing high levels of nitrates, like tacos, pizza, *etc.*[55]

572. The results of Valisure's tests on ranitidine tablets in biologically relevant

[55] *See, e.g.*, https://www.ispot.tv/ad/dY7n/zantac-family-taco-night; https://youtu.be/jzS2kuB5_wg; https://youtu.be/Z3QMwkSUlEg; https://youtu.be/qvh9gyWqQns.

conditions demonstrate significant NDMA formation under simulated gastric conditions with nitrite present (*see* Table 2).

Table 2 – Valisure Biologically Relevant Tests for NDMA Formation		
Ranitidine Tablet Studies	**NDMA (ng/mL)**	**NDMA per tablet (ng)**
Tablet without Solvent	Not Detected	Not Detected
Tablet	Not Detected	Not Detected
Simulated Gastric Fluid ("SGF")	Not Detected	Not Detected
Simulated Intestinal Fluid	Not Detected	Not Detected
SGF with 10 mM Sodium Nitrite	Not Detected	Not Detected
SGF with 25 mM Sodium Nitrite	236	23,600
SGF with 50 mM Sodium Nitrite	3,045	304,500

573. Under biologically relevant conditions, when nitrites are present, high levels of NDMA are found in one dose of 150 mg Zantac, ranging between 245 and 3,100 times above the FDA-allowable limit. In terms of smoking, one would need to smoke over 500 cigarettes to achieve the same levels of NDMA found in one dose of 150 mg Zantac at the 25 nanogram level (over 7,000 for the 50 nanogram level).

574. When the scientific data is assessed overall, the literature demonstrates that the ingestion of ranitidine in the presence of human-relevant levels of nitrite in the stomach—a substance that is commonly found in foods that induce heartburn and that is known to be elevated in people taking ranitidine for longer than a month—the ranitidine molecule breaks down into levels of NDMA that would dramatically increase

a person's risk of developing cancer.

B. Formation of NDMA in the Other Organs of Human Body

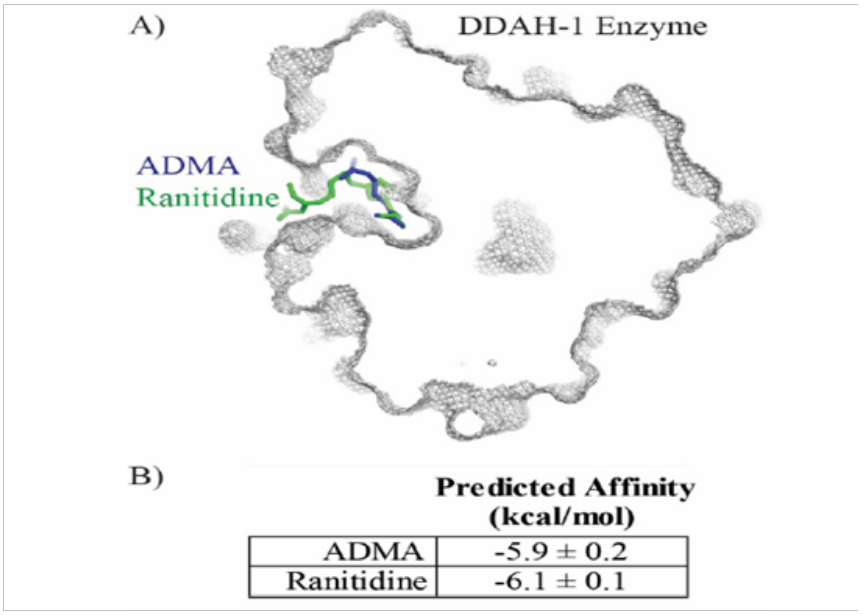
575. In addition to the gastric fluid mechanisms investigated in the scientific literature, Valisure identified a possible enzymatic mechanism for the liberation of ranitidine's DMA group via the human enzyme dimethylarginine dimethylaminohydrolase ("DDAH"), which can occur in other tissues and organs separate from the stomach.

576. Liberated DMA can lead to the formation of NDMA when exposed to nitrite present on the ranitidine molecule, nitrite freely circulating in the body, or other potential pathways, particularly in weak acidic conditions such as that in the kidney or bladder. The original scientific paper detailing the discovery of the DDAH enzyme in 1989 specifically comments on the propensity of DMA to form NDMA: "This report also provides a useful knowledge for an understanding of the endogenous source of dimethylamine as a precursor of a potent carcinogen, dimethylnitrosamine [NDMA]."[56]

577. In Figure 2, below, computational modelling demonstrates that ranitidine (shown in green) can readily bind to the DDAH-1 enzyme (shown as a cross-section in grey) in a manner similar to the natural substrate of DDAH-1 known as asymmetric dimethylarginine ("ADMA," shown in blue).

[56] Ogawa, *et al*., *Purification and properties of a new enzyme, NG, NG-dimethylarginine dimethylaminohydrolase, from rat kidney*, 264 *J. BIO. CHEM.* 17, 10205-10209 (1989).

Figure 2 – Computational Modelling of Ranitidine Binding to DDAH-1 Enzyme

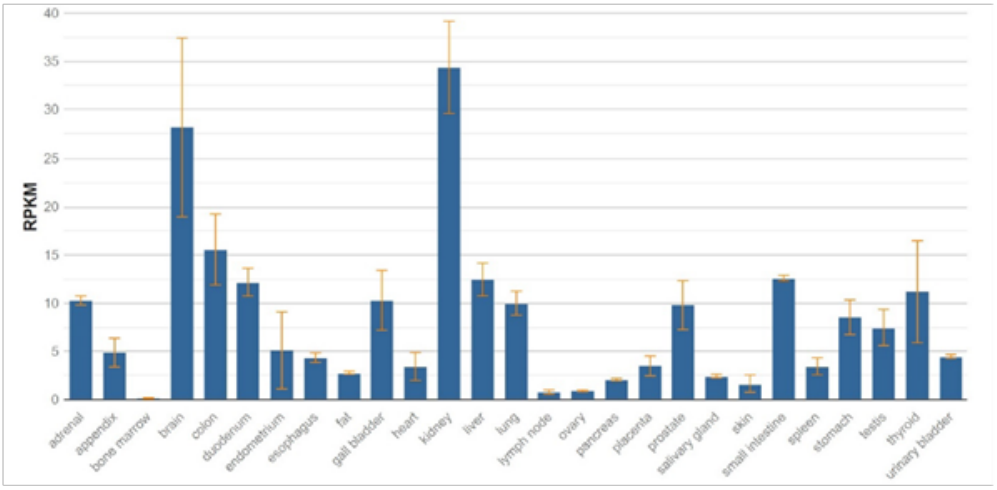


	Predicted Affinity (kcal/mol)
ADMA	-5.9 ± 0.2
Ranitidine	-6.1 ± 0.1

578. These results indicate that the enzyme DDAH-1 increases formation of NDMA in the human body when ranitidine is present; therefore, the expression of the DDAH-1 gene is useful for identifying organs most susceptible to this action.

579. Figure 3 below, derived from the National Center for Biotechnology Information, illustrates the expression of the DDAH-1 gene in various tissues in the human body.

Figure 3 – Expression levels of DDAH-1 enzyme by Organ



580. DDAH-1 is most strongly expressed in the kidneys but also broadly distributed throughout the body, such as in the liver, prostate, stomach, bladder, brain, colon, and prostate. This offers both a general mechanism for NDMA formation in the human body from ranitidine and specifically raises concern for the effects of NDMA on numerous organs, including the bladder.

581. The possible enzymatic reaction of ranitidine to DDAH-1, or other enzymes, suggests that high levels of NDMA can form throughout the human body. Indeed, ranitidine metabolizes and circulates throughout the human body, crossing the placental and blood-brain barrier, within 1-2 hours. When the ranitidine interacts with the DDAH-1 enzyme in various organs throughout the body, it breaks down into NDMA. This observation is validated by the Stanford study.

C. Formation of NDMA by Exposure to Heat and/or Time

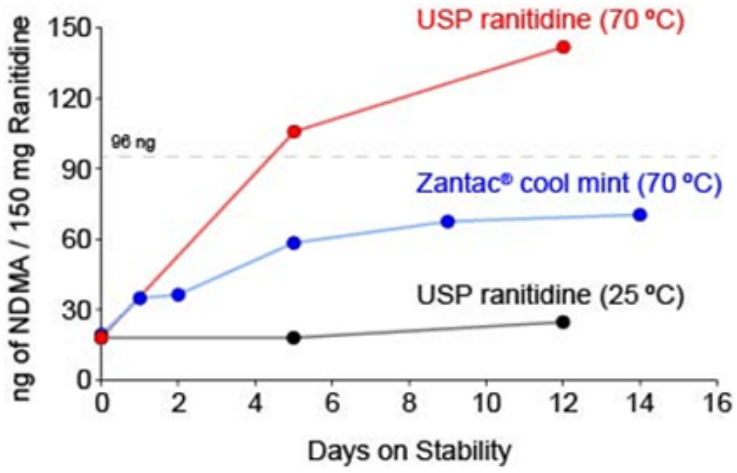
582. The risk of creating NDMA by exposing ranitidine to heat has been well-

known and documented. Early studies, including the one conducted by GSK in the early 1980s, demonstrated that NDMA formed when ranitidine was exposed to heat. This point was underscored in the Valisure petition, which specifically developed a detection protocol that did not use heat.

583. In response to Valisure, on October 2, 2019, the FDA recommended that researchers use the LC-HRMS protocol for detecting NDMA in ranitidine because the "testing method does not use elevated temperatures" and has been proven capable of detecting NDMA.

584. On January 2, 2020, Emery Pharma, an FDA-certified pharmaceutical testing laboratory, conducted a series of tests on ranitidine using the FDA-recommended LC-HRMS protocol. The researchers exposed ranitidine to 70 °C for varying periods of time. The results showed that increasing levels of NDMA formed based on exposure to heat. The following diagram reveals how NDMA accumulates over time when exposed to 70 °C:

Figure 4 – Rate of Development of NDMA when Exposed to Heat



585. The researchers cautioned:

> NDMA accumulates in ranitidine-containing drug products on exposure to elevated temperatures, which would be routinely reached during shipment and during storage. More importantly, these conditions occur post-lot release by the manufacturer. Hence, while NDMA levels in ranitidine may be acceptable at the source, they may not be so when the drug is purchased and subsequently at the time of consumption by the consumer.

586. Indeed, the FDA's recent testing confirms that NDMA levels increase in ranitidine even under normal storage conditions, and NDMA has been found to increase significantly in samples stored at higher temperatures, including temperatures to which ranitidine may be exposed during distribution and handling by retailers.[57]

587. Testing by Emery Pharma indicates on samples of Zantac products produced to it by GlaxoSmithKline, Boehringer Ingelheim, and Sanofi showed, on average, 1,530 ngs for each 150 mgs of ranitidine. For unexpired product, their testing revealed 1,096.6 ngs for each 150 mgs of ranitidine.

588. The results of this data demonstrate that in normal transport and storage, and especially when exposed to heat, the ranitidine molecule systematically breaks down into NDMA, accumulating over time in the finished product. Considering ranitidine-containing products have an approved shelf life of 36 months, the possibility

[57] Press Release, *FDA Requests Removal of All Ranitidine Products (Zantac) from the Market*, U.S. Food and Drug Administration (April 1, 2020), *available at* https://www.fda.gov/news-events/press-announcements/fda-requests-removal-all-ranitidine-products-zantac-market

of the drug accumulating dangerously high levels of NDMA prior to consumption is very real—a point underscored by the FDA's swift removal of the product from the market.

D. Evidence Also Directly Links Ranitidine Exposure to Cancer

589. In addition to numerous epidemiology studies examining how NDMA causes cancer in humans, researchers have also specifically looked at ranitidine and found an association with cancer.

590. One epidemiology study, published in 2004, showed that men taking either ranitidine or cimetidine (Tagamet) had increased risks of bladder cancer.[58]

591. In one epidemiology study specifically designed to look at breast cancer, ranitidine was shown to more than double the risk of breast cancer, an effect that was even more pronounced in those with specific gene mutations.[59]

592. In another comprehensive epidemiological study looking at various cancer risks and H2 blockers, including ranitidine, the data showed that ranitidine consumption increased the risk of prostate, lung, esophageal, pancreatic, and kidney cancer.[60] Of particular note, the study indicated that people under the age of 60 that took ranitidine were five times more likely to contract prostate cancer.

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[58] D. Michaud, et al, *Peptic Ulcer Disease and the Risk of Bladder Cancer in a Prospective Study of Male Health Professionals*, 13 CANCER EPI. BIOMARK. & PREV. 250–254, 252 (Feb. 2004).

[59] Robert W. Mathes, et al, *Relationship between histamine2-receptor antagonist medications and risk of invasive breast cancer*, 17 CANCER EPI. BIOMARKERS & PREVENTION 1, 67-72 (2008).

[60] Laurel A. Habel, et al, *Cimetidine Use and Risk of Breast, Prostate, and Other Cancers*, 9 PHARMACOEPIDEMOLOGY & DRUG SAFETY 149-155 (2000).

593. A study published in 2018, demonstrated an increased risk of liver cancer associated with use of ranitidine in comparison with other histamine type 2 receptor antagonists (H2RAs) in the class. The purpose of the study was to determine whether there was an increased risk of liver cancer associated with proton pump inhibitors, a different class of medications indicated for the treatment of GERD. This finding is particularly notable as the authors adjusted for variables and, more significantly, did not study or consider long term use of H2RAs or the possibility of a dose dependent increase in risk.[61]

594. In 2018, a study found an increased risk in hepatocellular carcinoma associated with use of H2RAs.[62] The authors were evaluating the risk of cancer in association with proton pump inhibitors and looked at H2RAs as a confounder. The study only considered use of H2RAs within one year of cancer diagnosis and still found an increased odds ratio associated with use of H2RAs and hepatocellular carcinoma, a type of liver cancer.

595. A number of other studies have been published over the years showing an increased risk of various cancers associated with use of ranitidine and/or H2RAs.[63]

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[61] Kim Tu Tran,, et al., *Proton pump inhibitor and histamine-2 receptor antagonist use and risk of liver cancer in two population-based studies*, 48 ALIMENTARY PHARMA & THERAP 1, 55-64 (2018).

[62] Shao, Y-HJ, et al., *Association between proton pump inhibitors and the risk of hepatocellular carcinoma*, 48 ALIMENTARY PHARMA & THERAP 4, 460-468 (2018).

[63] Robert W. Mathes, et al., *Relationship between histamine2-receptor antagonist medications and risk of invasive breast cancer*, 17 CANCER EPID. & PREV BIOMARKERS 1, 67-72 (2008); *see also* Ahn, Jeong Soo, et al., *Acid suppressive drugs and gastric cancer: a meta-analysis of observational studies*, 19 WORLD J. GASTROENTEROLOGY 16, 2560 (2013); Lai, Shih-Wei, et al., *Use of proton pump inhibitors correlates with increased risk of pancreatic cancer: a*

596. In addition, Memorial Sloan Kettering recently tested ranitidine for cancer association. In January 2021, a Sloan Kettering paper demonstrated an association with cancer that showed a "significant increase" in the odds of developing multiple types of cancer.

V. DEFENDANTS MADE FALSE STATEMENTS IN THE LABELING OF THEIR RANITIDINE-CONTAINING PRODUCTS

597. A manufacturer is required to give adequate directions for the use of a pharmaceutical drug such that a "layman can use a drug safely and for the purposes for which it is intended,"[64] and conform to requirements governing the appearance of the label.[65]

598. "Labeling" encompasses all written, printed or graphic material accompanying the drug or device,[66] and therefore broadly encompasses nearly every form of promotional activity, including not only "package inserts" but also advertising.

599. "Most, if not all, labeling is advertising. The term "labeling" is defined in the FDCA as including all printed matter accompanying any article. Congress did not, and we cannot, exclude from the definition printed matter which constitutes advertising."[67]

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case-control study in Taiwan, 46 KUWAIT MED J. 1, 44-48 (2014); Poulsen et al., *Proton Pump Inhibitors and risk of gastric cancer – a population based cohort study*, 100 BRITISH J CANCER 1503-1507 (2009); E Wennerström, *Acid-suppressing therapies and subsite-specific risk of stomach cancer*, 116 BRITISH J CANCER 9, 1234-1238 (2017).

[64] 21 C.F.R. § 201.5.

[65] 21 C.F.R. § 801.15.

[66] *Id*. 65 Fed. Reg. 14286 (March 16, 2000).

600. If a manufacturer labels a drug but omits ingredients, that renders the drug misbranded.[68]

601. Because Defendants did not disclose NDMA as an ingredient in the Ranitidine-Containing Products ingested by Plaintiffs, the subject drugs were misbranded.

602. It is unlawful to introduce a misbranded drug into interstate commerce.[69] Thus, the Ranitidine-Containing Products ingested by Plaintiffs were unlawfully distributed and sold.

VI. DEFENDANTS KNEW OR SHOULD HAVE KNOWN OF THE NDMA RISK

603. During the time that Defendants manufactured and sold Ranitidine-Containing Drugs in the United States, the weight of scientific evidence showed that Ranitidine-Containing Drugs exposed users to unsafe levels of NDMA. Defendants failed to disclose this risk to consumers on the drug's label—or through any other means—and Defendants failed to report these risks to the FDA.

604. Going back as far as 1981, two years before Zantac entered the market, research showed elevated rates of NDMA, when properly tested. This was known or should have been known by the Defendants or any other maker or distributor of ranitidine-containing products.

605. Defendants concealed the Zantac–NDMA link from consumers in part by

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[67] *U.S. v. Research Labs.,* 126 F.2d 42, 45 (9th Cir. 1942).

[68] 21 C.F.R. § 201.6; 201.10.

[69] 21 U.S.C. § 331(a).

not reporting it to the FDA, which relies on drug manufacturers (or others, such as those who submit citizen petitions) to bring new information about an approved drug like Ranitidine-Containing Drugs to the agency's attention.

606. Manufacturers of an approved drug are required by regulation to submit an annual report to the FDA containing, among other things, new information regarding the drug's safety pursuant to 21 C.F.R. § 314.81(b)(2):

607. The report is required to contain . . . [a] brief summary of significant new information from the previous year that might affect the safety, effectiveness, or labeling of the drug product. The report is also required to contain a brief description of actions the applicant has taken or intends to take as a result of this new information, for example, submit a labeling supplement, add a warning to the labeling, or initiate a new study.

608. 21 C.F.R. § 314.81(b)(2)(v) provides:

> The manufacturer's annual report also must contain copies of unpublished reports and summaries of published reports of new toxicological findings in animal studies and in vitro studies (*e.g.*, mutagenicity) conducted by, or otherwise obtained by, the [manufacturer] concerning the ingredients in the drug product.

609. Defendants ignored these regulations and, disregarding the scientific evidence available to them, did not report to the FDA significant new information affecting the safety or labeling of Ranitidine-Containing Drugs.

610. Knowledge regarding the risk of NDMA in ranitidine was sufficiently available in the publicly available scientific literature that any maker or distributor, consistent with their heightened obligations to ensure the safety of their products,

should have known about the potential NDMA risks associated with ranitidine consumption.

611. Defendants never conducted or provided the relevant studies to the FDA, nor did they present to the FDA with a proposed disclosure noting the link between ranitidine and NDMA. Accordingly, because the Defendants never properly disclosed the risk to the FDA, they never proposed any labeling or storage / transportation guidelines that would have addressed this risk. Thus, the FDA was never able to reject any proposed warning or proposal for transport / storage.

612. Nothing prevented any Defendant from, on its own, taking actions to prevent accumulation of NDMA in ranitidine drugs by ensuring cooled storage and transport. Such actions would not have required FDA approval, nor would they have violated any regulatory decisions or laws.

613. Defendants also knew federal law requires pharmaceutical drugs to be stored, warehoused, and distributed in accordance with current "Good Manufacturing Practices" ("GMPs") to ensure they meet safety, quality, purity, identity, and strength standards. *See* 21 U.S.C. § 351(a)(2)(B).

614. 21 C.F.R. § 211.142(b) states that the GMPs required that warehousing of drug products shall be performed to provide for "[s]torage of drug products under appropriate conditions of temperature, humidity, and light so that the identity, strength, quality, and purity of the drug products are not affected." In other words, Defendants had a duty and were obligated to properly store, handle, and warehouse Ranitidine-Containing Drugs.

615. Testing conducted by the FDA, which led to the agency's ban on Ranitidine-Containing Drugs, confirms that improper storage of Ranitidine-Containing Drugs has resulted in extremely high levels of NDMA. FDA has also concluded that NDMA can increase in Ranitidine-Containing Drugs even under normal storage conditions. And, NDMA has been found to increase significantly in samples stored at higher temperatures, including temperatures the product may be exposed to during distribution and handling by consumers. FDA's testing also showed that as Ranitidine-Containing Drugs age the level of NDMA in the product increases.

616. FDA concluded that these defects raised the level of NDMA in Ranitidine-Containing Drugs above the acceptable daily intake limit to the point that the drugs had to be banned.

617. In a 1981 study published by GSK, the originator of the ranitidine molecule, the metabolites of ranitidine in urine were studied using liquid chromatography.[70] Many metabolites were listed, though there is no indication that NDMA was looked for. Plaintiffs believes this was intentional—a gambit by the manufacturer to avoid detecting a carcinogen in their product. All Defendants knew or should have known about this study and, therefore, were obligated to investigate this issue properly. None did.

618. Indeed, in that same year, Dr. de Flora published a note in The Lancet discussing the results of his experiments showing that ranitidine was turning into

[70] Carey, *et al*., *Determination of ranitidine and its metabolites in human urine by reversed-phase ion-pair high-performance liquid chromatography*, 255 J. CHROMATOGRAPHY B: BIOMEDICAL SCI. & APPL. 1, 161-168 (1981).

mutagenic N-nitroso compounds, of which NDMA is one, in human gastric fluid when accompanied by nitrites – a substance commonly found in food and in the body. GSK was aware of this as GSK specifically responded to the note and attempted to discredit it. Defendants knew or should have known about this scientific exchange as it was in a popular scientific journal, The Lancet. Therefore, the Defendants were obligated to investigate this issue properly, and none did.

619. By 1987, after numerous studies raised concerns over ranitidine and cancerous nitroso compounds (discussed previously), GSK published a clinical study specifically investigating gastric contents in human patients and N-nitroso compounds.[71] This study specifically indicated that there were no elevated levels of N-nitroso compounds (of which NDMA is one). However, the study was rigged to fail. It used an analytical system called a "nitrogen oxide assay" for the determination of N-nitrosamines, which was developed for analyzing food and is a detection method that indirectly and non-specifically measures N-nitrosamines. Furthermore, in addition to this approach being less accurate, GSK also removed all gastric samples that contained ranitidine out of concern that samples with ranitidine would contain "high concentrations of N-nitroso compounds being recorded." So, without the chemical being present in any sample, any degradation into NDMA could not, by design, be observed. Again, this spurious test was intentional and designed to mask any potential cancer risk. The inadequacy of this test was knowable in light of its scientific

[71] Thomas, *et al*., *Effects of one year's treatment with ranitidine and of truncal vagotomy on gastric contents*, 6 *GUT*. Vol. 28, 726-738 (1987).

publication in 1987. All Defendants either knew or should have known about the inadequacy of this study and should have investigated the issue properly and/or took action to protect consumers from the NDMA risks in their products. None did.

620. In fact, upon information and belief, none of the Defendants ever used a mass spectrometry assay to test for the presence of nitrosamines in any of the studies and trials they did in connection with their trials associated with the ranitidine NDA. That is because when using mass spectrometry, it requires heating of up to 130 degrees Celsius, which can result in excessive amounts of nitrosamines being formed. Had the Defendants used a mass spectrometry assay, it would have revealed in the finding of large amounts of NDMA, and the FDA would never have approved Zantac as being safe.

621. Based on the public scientific information available starting in 1983 (or earlier), the Defendants knew or should have known that NDMA could form in ranitidine by exposure to heat and/or over time in storage. No Defendants, upon information and belief, took action to reduce this risk through altering supply-chain conduct or warning consumers. Additionally, no Defendants took any action to further investigate this issue notwithstanding the signal that existed in the scientific literature.

622. Although the labels for Ranitidine-Containing Drugs do not warn of any NDMA or cancer risk, Defendants were aware of the dangers of exposing Ranitidine-Containing Drugs to excess heat– but failed to take steps to reduce NDMA accumulation –given that each Zantac *box* states, "to avoid excessive heat" and to keep the drug below 77˚F:


Other information
- do not use if individual foil pouch is open or torn
- avoid excessive heat or humidity
- store at 20°-25°C (68°-77°F)
- this product is sodium and sugar free

623. Any distributor or seller of a Ranitidine-Containing Drug would be duty-bound to follow the handling procedures and ensure the product is not exposed to temperatures above 77° F during transport and storage.

624. There are multiple alternatives to Zantac that do not pose the same risk, such as Cimetidine (Tagamet), Famotidine (Pepcid), Omeprazole (Prilosec), Esomeprazole (Nexium), and Lansoprazole (Prevacid).

VII. EXEMPLARY / PUNITIVE DAMAGES ALLEGATIONS (AGAINST MANUFACTURER DEFENDANTS)

625. Defendants' conduct as alleged herein was done with reckless disregard for human life, oppression, and malice. Defendants were fully aware of the safety risks of Ranitidine-Containing Drugs, particularly the carcinogenic potential of Ranitidine-Containing Drugs as it transforms into NDMA within the chemical environment of the human body and/or during transport and/or storage. Nonetheless, Defendants deliberately crafted their label, marketing, and promotion to mislead consumers.

626. This was not done by accident or through some justifiable negligence. Rather, Defendants knew they could profit by convincing consumers that Ranitidine-Containing Drugs was harmless to humans, and that full disclosure of the true risks of Ranitidine-Containing Drugs would limit the amount of money Defendants would make selling the drugs. Defendants' object was accomplished not only through a misleading label, but through a comprehensive scheme of selective misleading research and testing, false advertising, and deceptive omissions as more fully alleged throughout

this pleading. Plaintiffs was denied the right to make an informed decision about whether to purchase and use Ranitidine-Containing Drugs, knowing the full risks attendant to that use. Such conduct was done with conscious disregard of Plaintiffs' rights.

627. Accordingly, Plaintiffs requests punitive damages against the Manufacturer Defendants for the harms caused to Plaintiffs.

VIII. EQUITABLE TOLLING/ESTOPPEL

628. Plaintiffs asserts all applicable statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, delayed discovery, discovery rule and/or fraudulent concealment.

629. The discovery rule applies to toll the running of the statute of limitations until Plaintiffs knew, or through the exercise of reasonable care and diligence should have known, of facts that Plaintiffs had been injured, the cause of the injury, and the tortious nature of the wrongdoing that caused the injury.

630. The nature of Plaintiffs' injuries, damages, or Plaintiffs' causal relationship to Defendants' conduct was not discovered, and through reasonable care and due diligence could not have been discovered until a date within the applicable statute of limitations for filing Plaintiffs' claims.

631. The running of the statute of limitations is tolled due to equitable tolling. Defendants are estopped from relying on any statutes of limitation or repose by virtue of their acts of fraudulent concealment, through affirmative misrepresentations and

omissions to Plaintiffs and defects associated with Ranitidine-Containing Drugs including the severity, duration, and frequency of risks and complications. Defendants affirmatively withheld and/or misrepresented facts concerning the safety of Ranitidine-Containing Drugs. As a result of Defendants' misrepresentations and concealment, Plaintiffs could not have known or have learned through reasonable diligence that Plaintiffs had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and/or omissions of the Defendants.

632. Given Defendants' affirmative actions of concealment by failing to disclose this known but non-public information about the defects – information over which the Defendants had exclusive control – and because Plaintiffs could not reasonably have known that Ranitidine-Containing Drugs were and are defective, Defendants are estopped from relying on any statutes of limitations or repose that might otherwise be applicable to the claims asserted herein.

CAUSES OF ACTION

COUNT I: STRICT PRODUCTS LIABILITY – FAILURE TO WARN

633. Plaintiffs incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

634. At all relevant times, Defendants engaged in the business of researching, testing, developing, designing, manufacturing, labeling, marketing, selling, inspecting, handling, storing, distributing, and promoting Ranitidine-Containing Drugs, which are defective and unreasonably dangerous to consumers, including Plaintiffs, because they do not contain adequate warnings or instructions concerning the dangerous

characteristics of Ranitidine-Containing Drugs and NDMA. These actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Ranitidine-Containing Drugs and aimed at a consumer market.

635. Defendants researched, tested, developed, designed, manufactured, labeled, marketed, sold, inspected, handled, stored, distributed, and promoted, and otherwise released into the stream of commerce their Ranitidine-Containing Drugs, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiffs, and therefore had a duty to warn of the risks associated with the use of Ranitidine-Containing Drugs.

636. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, handle, store, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure their Ranitidine-Containing Drugs did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiffs of dangers associated with Ranitidine-Containing Drugs. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

637. Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper storage and handling of Ranitidine-Containing Drugs.

638. At the time of manufacture, Defendants could have provided the warnings or instructions regarding the full and complete risks of Ranitidine-Containing

Drugs because they knew or should have known of the unreasonable risks of harm associated with the use of and/or exposure to such products.

639. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety or to minimize the dangers to users and consumers of their product and to those who would foreseeably use or be harmed by Defendants' Ranitidine-Containing Drugs.

640. Even though Defendants knew or should have known that Ranitidine-Containing Drugs posed a grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to the drugs. The dangerous propensities of their products and the carcinogenic characteristics of NDMA as produced within the human body as a result of ingesting Ranitidine-Containing Drugs, as described above, were known to Defendants, or scientifically knowable to Defendants through appropriate research and testing by known methods, at the time they distributed, supplied or sold the product, and were not known to end users and consumers, such as the Plaintiffs.

641. Defendants knew or should have known that their products created significant risks of serious bodily harm to consumers, as alleged herein, and Defendants failed to adequately warn or instruct consumers, *i.e.*, the reasonably foreseeable users, of the risks of exposure to their products. Defendants failed to warn and have wrongfully concealed information concerning the dangerous level of NDMA in their Ranitidine-Containing Drugs and the potential for ingested Ranitidine-Containing Drugs to transform into the carcinogenic NDMA compound, and further, have made false

and/or misleading statements concerning the safety of Ranitidine-Containing Drugs.

642. At all relevant times, Defendants' Ranitidine-Containing Drugs reached the intended consumers, handlers, and users or other persons coming into contact with these products, including Plaintiffs, without substantial change in their condition as designed, manufactured, sold, distributed, labeled, and marketed by Defendants.

643. Plaintiffs was exposed to Defendants' Ranitidine-Containing Drugs without knowledge of their dangerous characteristics.

644. At all relevant times, Plaintiffs used and/or was exposed to the use of Defendants' Ranitidine-Containing Drugs while using them for their intended or reasonably foreseeable purposes, without knowledge of their dangerous characteristics.

645. Plaintiffs could not have reasonably discovered the defects and risks associated with Ranitidine-Containing Drugs prior to or at the time of Plaintiffs consuming Zantac. Plaintiffs relied upon the skill, superior knowledge, and judgment of Defendants to know about and disclose serious health risks associated with using Defendants' products.

646. Defendants knew or should have known that the minimal warnings disseminated with their Ranitidine-Containing Drugs were inadequate, failed to communicate adequate information on the dangers and safe use/exposure, and failed to communicate warnings and instructions that were appropriate and adequate to render the products safe for their ordinary, intended and reasonably foreseeable uses.

647. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled

consumers such as Plaintiffs to avoid using the drug. Instead, Defendants disseminated information that was inaccurate, false, and misleading, and which failed to communicate accurately or adequately the comparative severity, duration, and extent of the risk of injuries with use of and/or exposure to Ranitidine-Containing Drugs; continued to aggressively promote the efficacy of their products, even after they knew or should have known of the unreasonable risks from use or exposure; and concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Ranitidine-Containing Drugs.

648. This alleged failure to warn is not limited to the information contained on Ranitidine-Containing Drugs' labeling. The Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with Ranitidine-Containing Drugs through other non-labeling mediums, *i.e.*, promotion, advertisements, public service announcements, and/or public information sources. But the Defendants did not disclose these known risks through any medium.

649. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Ranitidine-Containing Drugs, Plaintiffs could have avoided the risk of developing injuries and could have obtained or used alternative medication. However, as a result of Defendants' concealment of the dangers posed by their Ranitidine-Containing Drugs, Plaintiffs could not have averted Plaintiffs' injuries.

650. Defendants' conduct, as described above, was reckless. Defendants risked

the lives of consumers and users of their products, including Plaintiffs, with knowledge of the safety problems associated with Ranitidine-Containing Drugs, and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, warn or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

651. The Defendants' lack of adequate warnings and instructions accompanying their Ranitidine-Containing Drugs were a substantial factor in causing Plaintiffs' injuries.

652. As a direct and proximate result of the Defendants' failure to provide an adequate warning of the risks of Ranitidine-Containing Drugs, Plaintiffs has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to past and future medical expenses, lost income, and other damages.

COUNT II: STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

653. Plaintiffs incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

654. At all times herein mentioned, Defendants designed, manufactured, tested, marketed, sold, handled, distributed, and stored the Ranitidine-Containing Drugs ingested by Plaintiffs to patients and physicians.

655. At all relevant times, the medication ingested by Plaintiffs was expected to and did reach Plaintiffs without a substantial change in its condition as manufactured, handled, distributed, stored, and sold by Defendants.

656. At all relevant times, the medications ingested by Plaintiffs were used in a manner that was foreseeable and intended by Defendants.

657. The Ranitidine-Containing Drugs ingested by Plaintiffs were not reasonably safe for their intended use and were defective with respect to their manufacture, as described herein, in that Defendants deviated materially from their design, manufacturing, handling, and storage specifications and/or such design, manufacture, storage, and handling posed an unreasonable risk of harm to Plaintiffs.

658. The Defendants' Ranitidine-Containing Drugs are inherently dangerous and defective, unfit and unsafe for its intended and reasonably foreseeable uses, and do not meet or perform to the expectations of patients and their health care providers.

659. The Ranitidine-Containing Drugs create risks to the health and safety of the patients that are far more significant and devastating than the risks posed by other products and treatments available to treat the corresponding medical conditions, and which far outweigh the utility of the ranitidine-containing products because of Defendants' manufacturing defects, which included but were not limited to:

a. Failure to follow Good Manufacturing Practices;

b. Failure to adequately inspect/test the drugs during the manufacturing process;

c. Failure to implement procedures that would reduce or eliminate NDMA levels in Ranitidine-Containing Drugs;

d. Failure to implement appropriate handling instructions and storage conditions for the drug.

660. Defendants have intentionally and recklessly manufactured the Ranitidine-Containing Drugs with wanton and willful disregard for the rights and health of the Plaintiffs, and with malice, placing their economic interests above the health and safety of the Plaintiffs.

661. The manufacturing defects in Defendants' Ranitidine-Containing Drugs were substantial factors in causing Plaintiffs' injuries

662. As a direct and proximate result of the Defendants' defective manufacture of the Ranitidine-Containing Drugs, Plaintiffs has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to medical expenses, lost income, and other damages.

COUNT III: NEGLIGENCE – FAILURE TO WARN

663. Plaintiffs incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

664. At all relevant times, Defendants engaged in the business of testing, developing, designing, manufacturing, marketing, selling, handling, storing, distributing, and promoting Ranitidine-Containing Drugs. Defendants knew or by the exercise of reasonable care should have known that their Ranitidine-Containing Drugs are not accompanied with adequate warnings or instructions concerning the dangerous characteristics of Ranitidine-Containing Drugs and NDMA. These actions were under the ultimate control and supervision of Defendants.

665. Defendants researched, developed, designed, tested, manufactured,

inspected, labeled, handled, stored, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce their Ranitidine-Containing Drugs, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiffs, and therefore had a duty to warn of the risks associated with the use of Ranitidine-Containing Drugs.

666. At all relevant times, Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, handle, store, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure their Ranitidine-Containing Drugs did not cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to warn Plaintiffs of dangers associated with Ranitidine-Containing Drugs. Defendants, as a manufacturer, seller, or distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

667. Defendants had a continuing duty to provide appropriate and accurate instructions regarding the proper storage and handling of Ranitidine-Containing Drugs.

668. At the time of manufacture, Defendants could have provided warnings or instructions regarding the full and complete risks of Ranitidine-Containing Drugs because they knew or should have known use of Ranitidine-Containing Drugs was dangerous, harmful and injurious when used by Plaintiffs in a reasonably foreseeable manner.

669. At all relevant times, Defendants failed and deliberately refused to investigate, study, test, or promote the safety or to minimize the dangers to users and

consumers of their product and to those who would foreseeably use or be harmed by Defendants' Ranitidine-Containing Drugs.

670. Defendants knew or should have known that Ranitidine-Containing Drugs posed a grave risk of harm but failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure to the products. The dangerous propensities of their products and the carcinogenic characteristics of NDMA as produced within the human body as a result of ingesting Ranitidine-Containing Drugs, as described above, were known to Defendants, or scientifically knowable to Defendants through appropriate research and testing by known methods, at the time they distributed, supplied or sold the product, and were not known to end users and consumers, such as the Plaintiffs.

671. Defendants further breached their duty by failing to use reasonable care to adequately warn or instruct consumers (*i.e.*, the reasonably foreseeable users) of the risks of exposure to their products. Defendants failed to warn and have wrongfully concealed information concerning the dangerous level of NDMA in their Ranitidine-Containing Drugs and the potential for ingested Ranitidine-Containing Drugs to transform into the carcinogenic NDMA compound, and further, have made false and/or misleading statements concerning the safety of Ranitidine-Containing Drugs.

672. At all relevant times, Plaintiffs used and/or was exposed to excessive levels of NDMA through the use of Defendants' Ranitidine-Containing Drugs while using them for their intended or reasonably foreseeable purposes, without knowledge of their dangerous characteristics.

673. Defendants knew or should have known that the minimal warnings disseminated with their Ranitidine-Containing Drugs were inadequate, failed to communicate adequate information on the dangers and safe use/exposure, and failed to communicate warnings and instructions that were appropriate and adequate to render the products safe for their ordinary, intended and reasonably foreseeable uses.

674. The information that Defendants did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiffs to avoid using the product. Instead, Defendants disseminated information that was inaccurate, false, and misleading, and which failed to communicate accurately or adequately the comparative severity, duration, and extent of the risk of injuries with use of and/or exposure to Ranitidine-Containing Drugs; continued to aggressively promote the efficacy of their products, even after they knew or should have known of the unreasonable risks from use or exposure; and concealed, downplayed, or otherwise suppressed, through aggressive marketing and promotion, any information or research about the risks and dangers of ingesting Ranitidine-Containing Drugs.

675. A reasonable company under the same or similar circumstance would have warned and instructed of the dangers of Ranitidine-Containing Drugs.

676. This alleged failure to warn is not limited to the information contained on Ranitidine-Containing Drugs' labeling. The Defendants were able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with Ranitidine-Containing Drugs through other non-labeling mediums, *i.e.*,

promotion, advertisements, public service announcements, and/or public information sources. But the Defendants did not disclose these known risks through any medium.

677. Had Defendants provided adequate warnings and instructions and properly disclosed and disseminated the risks associated with their Ranitidine-Containing Drugs, Plaintiffs could have avoided the risk of developing injuries and could have obtained or used alternative medication. However, as a result of Defendants' concealment of the dangers posed by their Ranitidine-Containing Drugs, Plaintiffs could not have averted Plaintiffs' injuries.

678. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of their products, including Plaintiffs, with knowledge of the safety problems associated with Ranitidine-Containing Drugs, and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, warn or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

679. The Defendants' lack of adequate warnings and instructions accompanying their Ranitidine-Containing Drugs were a substantial factor in causing Plaintiffs' injuries.

680. As a direct and proximate result of the Defendants' failure to provide an adequate warning of the risks of Ranitidine-Containing Drugs, Plaintiffs has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to past and future medical expenses, lost income, and other damages.

COUNT IV: NEGLIGENT PRODUCT DESIGN

681. The Defendants knew or, by the exercise of reasonable care, should have known, ordinary consumers such as Plaintiffs would not have realized the potential risks and dangers of Ranitidine-Containing Drugs.

682. The Defendants owed a duty to all reasonably foreseeable users to design a safe product.

683. The Defendants breached their duty by failing to use reasonable care in the design of Ranitidine-Containing Drugs because the drug exposed users to unsafe levels of the carcinogen NDMA.

684. The Defendants breached their duty by failing to use reasonable care in the design of Ranitidine-Containing Drugs by negligently designing the drug with an inherent susceptibility to form NDMA.

685. The Defendants breached their duty by failing to use reasonable care in the design of Ranitidine-Containing Drugs by negligently designing in design and formulation, in one or more of the following ways:

a. When placed in the stream of commerce, Defendants' Ranitidine-Containing Drugs were defective in design and formulation, and, consequently, dangerous to an extent beyond that which an ordinary consumer would contemplate;

b. When placed in the stream of commerce, Defendants' Ranitidine-Containing Drugs were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer and other serious

illnesses when used in a reasonably anticipated manner;

c. When placed in the stream of commerce, Defendants' Ranitidine-Containing Drugs contained unreasonably dangerous design defects and were not reasonably safe when used in a reasonably anticipated or intended manner;

d. Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Drugs and, specifically, the ability for Ranitidine-Containing Drugs to transform into the carcinogenic compound NDMA within the human body;

e. Defendants did not sufficiently test, investigate, or study their Ranitidine-Containing Drugs and, specifically, the ability for Ranitidine-Containing Drugs to develop increasing levels of NDMA over time under anticipated and expected storage and handling conditions;

f. Exposure to Ranitidine-Containing Drugs presents a risk of harmful side effects that outweigh any potential utility stemming from the use of the drug;

g. Defendants knew or should have known at the time of marketing Ranitidine-Containing Drugs that exposure to Ranitidine-Containing Drugs could result in cancer and other severe illnesses and injuries;

h. Defendants did not conduct adequate post-marketing surveillance

of their Ranitidine-Containing Drugs; and

i. Defendants could have employed safer alternative designs and formulations. For example, the Defendants could have added ascorbic acid (Vitamin C) to each dose of Ranitidine-Containing Drugs, which is known to scavenge nitrites and reduce the ability of the body to recombine ranitidine into NDMA.

686. The Defendants breached their duty by failing to use reasonable care by failing to use cost effective, reasonably feasible alternative designs. there was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' Ranitidine-Containing Drugs.

687. A reasonable company under the same or similar circumstances would have designed a safer product.

688. Plaintiffs was harmed directly and proximately by the Defendants' failure to use reasonable care in the design of their Ranitidine-Containing Drugs. Such harm includes significant exposure to a known carcinogen, NDMA, which can cause or contribute the development of cancers.

689. Defendants' defective design of Ranitidine-Containing Drugs was willful, wanton, malicious, and conducted with reckless disregard for the health and safety of users of the Ranitidine-Containing Drugs, including Plaintiffs.

690. The defects in Defendants' Ranitidine-Containing Drugs were substantial factors in causing Plaintiffs' injuries.

691. As a direct and proximate result of the Defendants' defective design of the Ranitidine-Containing Drugs, Plaintiffs has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to past and future medical expenses, lost income, and other damages.

COUNT V: NEGLIGENT MANUFACTURING

692. Plaintiffs incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

693. At all relevant times, the Defendants manufactured, tested, marketed, sold, handled, distributed and stored the Ranitidine-Containing Drugs that Plaintiffs consumed.

694. The Defendants had a duty to exercise reasonable care, in the manufacturing, testing, marketing, sale, handling, storing, packaging, and distribution of Ranitidine-Containing Drugs.

695. The Defendants knew or, by the exercise of reasonable care, should have known, use of Ranitidine-Containing Drugs were carelessly manufactured, packaged was dangerous, harmful and injurious when used by Plaintiffs in a reasonably foreseeable manner.

696. The Defendants knew or, by the exercise of reasonable care, should have known, ordinary consumers such as Plaintiffs would not have realized the potential risks and dangers of Ranitidine-Containing Drugs improperly manufactured, tested, marketed, sold, handled, distributed, and stored.

697. Without limitation, examples of the manner in which Defendants breached their duty to exercise reasonable care in manufacturing Ranitidine-Containing Drugs, included:

a. Failure to follow Good Manufacturing Practices;

b. Failure to adequately inspect/test the drugs during the manufacturing process;

c. Failure to implement procedures that would reduce or eliminate NDMA levels in Ranitidine-Containing Drugs; and

d. Failure to implement appropriate handling instructions and storage conditions for the drug.

698. A reasonable manufacturer under the same or similar circumstances would have implemented appropriate manufacturing procedures to better ensure the quality and safety of their product.

699. Plaintiffs was harmed directly and proximately by the Defendants' failure to use reasonable care in the manufacture of their Ranitidine-Containing Drugs. Such harm includes significant exposure to a known carcinogen, NDMA, which can cause or contribute the development of cancers.

700. Defendants' improper manufacturing of Ranitidine-Containing Drugs was willful, wanton, malicious, and conducted with reckless disregard for the health and safety of users of the Ranitidine-Containing Drugs, including Plaintiffs.

701. The defects in Defendants' Ranitidine-Containing Drugs were substantial factors in causing Plaintiffs' injuries.

702. As a direct and proximate result of the Defendants' improper manufacturing of Ranitidine-Containing Drugs, Plaintiffs has been injured, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but not limited to past and future medical expenses, lost income, and other damages.

COUNT VI: NEGLIGENT MISREPRESENTATION

703. Plaintiffs incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

704. At all relevant times, Defendants designed, manufactured, tested (or not), packaged, labeled, marketed, advertised, promoted, supplied, stored, handled, warehoused, distributed, sold and/or otherwise placed Ranitidine Containing Drugs into the stream of commerce, and therefore owed a duty of reasonable care to avoid causing harm to those that consumed Ranitidine-Containing Drugs, such as Plaintiffs.

705. Defendants were negligent, reckless, and careless and owed a duty to Plaintiffs to make accurate and truthful representations regarding Ranitidine Containing Drugs, Defendants breached their duty, thereby causing Plaintiffs to suffer harm.

706. Defendants represented to Plaintiffs via the media, advertising, website, social media, packaging, and promotions, among other misrepresentations described herein that:

707. Ranitidine-Containing Drugs were both safe and effective for the lifetime of the product, when in fact, the drug contains unsafe levels of NDMA far in excess of

the 96-ng limit that increases as the product ages;

708. Consumption of Ranitidine-Containing Drugs would not result in excessive amounts of NDMA being formed in their bodies; and

709. The levels of NDMA in Ranitidine-Containing Drugs have no practical clinical significance; and

710. Ranitidine-Containing Drugs were safe for their intended use when, in fact, Defendants knew or should have known the products were not safe for their intended purpose.

711. These representations were false. Because of the unsafe levels of NDMA in Ranitidine-Containing Drugs, the drug presented an unacceptable risk of causing cancer. Ranitidine-Containing Drugs are so unsafe that the FDA was compelled to order the immediate ban of all Ranitidine-Containing Drugs on April 1, 2020.

712. Defendants knew or should have known these representations were false and negligently made them without regard for their truth.

713. Defendants had a duty to accurately provide this information to Plaintiffs. In concealing this information from Plaintiffs, Defendants breached their duty. Defendants also gained financially from, and as a result of their breach.

714. Defendants intended for Plaintiffs to rely on these representations.

715. Each of these misrepresentations were material at the time they were made. In particular, each of the misrepresentations concerned material facts that were essential to the analysis undertaken by Plaintiffs as to whether to purchase or consume Ranitidine Containing Drugs.

716. Defendants have yet to correct these misrepresentations about Ranitidine-Containing Drugs.

717. Plaintiffs reasonably relied on these representations and was harmed as described herein. Plaintiffs' reliance on Defendants' representation was a substantial factor in causing Plaintiffs' harms. Had Defendants told Plaintiffs the truth about the safety and composition of Ranitidine-Containing Drugs, Plaintiffs would not have consumed or purchased them.

718. Defendants' acts and omissions as described herein were committed in reckless disregard of Plaintiffs' rights, interests, and well-being to enrich Defendants.

719. Plaintiffs was injured as a direct and proximate result of Defendants' negligent misrepresentations regarding Ranitidine-Containing Drugs as described herein.

JURY TRIAL DEMAND

720. Plaintiffs demands a trial by jury on all the triable issues within this pleading.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs requests the Court to enter judgment in Plaintiffs' favor and against the Defendants for:

a. actual or compensatory damages in such amount to be determined at trial and as provided by applicable law;

b. exemplary and punitive damages sufficient to punish and deter the Defendants and others from future wrongful practices;

c. pre-judgment and post-judgment interest;

d. costs including reasonable attorneys' fees, court costs, and other litigation expenses; and

e. such other and further relief the Court may deem just and proper.

Dated: August 5, 2022

CONAWAY-LEGAL LLC

/s/ Bernard G. Conaway

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General Information

Case Name	Barbara Allison v. GlaxoSmithKline
Court	Delaware Superior Court
Date Filed	Thu Aug 18 00:00:00 EDT 2022
Judge(s)	Vivian L. Medinilla
Docket Number	N22C-08-173
Parties	James Logan; Elvin Parker; Joseph Landrum; Tracy Greer; James Madore; Billy Spearman; Teresa Hutcheson; Ronnie Ellison; Harriett Rideeoutte; Cosmo Giusti; Jeffery Curtis; Joseph Garcia; Al Williams; Jeffrey Wonser; Leroy Brackett; Patheon Manufacturing Services LLC; Kerry Rivera; Nadine Oglesby; Linda Di Maria; Scott Maziarz; Dawn Wagster; Anna Braswell; Kerry Schlei; Michael Johnson; Leodis Conner; Lillian Henry; Mark Kelly; Terry Smith; Domenic Bernabei; Mary Gallant; Richard Jarer; Cindy Yapp; Arlene Moore; Joan Fusco; Dewey Patterson; Dirk Monger; Pearlie Johnson; Michael Paige; GlaxoSmithKline, LLC; Pfizer, Inc; Manuel Madrid; Boyce Sharpe; Jerald Thompson; Martha Adkins; Bruce Pollard; Marie Magarelli; Damon Smith; Leon Lindquist Jr.; Ray Sellers Jr.; Wilbert Roundtree; Boehringer Ingelheim USA Corporation; Robert Neal; Bobby Pearl; Theresa Hodgdon; Yvonne Roper; Cheryl Langer; Robert Yates; Gloria Smith; Margie Stam; Johnny Vollers; Kornelia Schreiter; Marilynne Harrison; Wendy Robinson; Cordelia Dickens; Russel Krause; Douglas Perritt; Mildred Kelly; Sharon Gilbertson; Christine Thomas; Jimmy McCarley; Sandy Brewer; John Ryder; Ronnie Lewis; Phillip Dugan; Amber Hamilton-Roberts; Sanofi-Aventis U.S. LLC; James Henderson; Glenn Skenadore; Tommie Franklin; Barbara Allison; Sanofi U.S. Services,

Inc.; Boehringer Ingelheim Pharmaceuticals, Inc.; Dennis Dubuque; Dreama Brant; William Shelly; Janet Sheppard; Karen Maestas; Charles Parrott; Ronald Coleman; Victoria Robbins; Greg Barber; Judy Craft; Glen Wilson; Emily Use; Angela Raskell; Richard Godbout; Daniel Rusher

SUPERIOR COURT
CIVIL CASE INFORMATION STATEMENT (CIS)

COUNTY: **N** K S CIVIL ACTION NUMBER: _____

Caption:
Barbara Allison, et al.

Plaintiffs,

v.

GlaxoSmithKline, et al.

Defendants.

Civil Case Code: CPRL

Civil Case Type: Products Liability
(See Reverse Side for Code and Type)

Mandatory Non-Binding Arbitration (MNA) n/a

Name and Status of Party filing document:

Document Type:(e.g.; Complaint; Answer with Counterclaim)
Complaint

Jury Demand: Yes X No ____

Attorney Name(s):
Bernard G. Conaway Esquire

Attorney ID(s):
2856

Firm Name:
Conaway-Legal LLC

Address:
1007 North Orange Street, Suite 400

Wilmington, DE 19801

Telephone Number:
(302) 428-9350

Fax Number:
(844) 364-0137

E-Mail Address:
bgc@conaway-legal.com

Identify any related cases now pending in the Superior Court or any related cases that have been closed in this court within the last two years by caption and civil action number including judge's initials:
See Exhibit 1

Explain the relationship(s):
Related to Zantac usage – same legal claims/injury

Other unusual issues that affect Case Management:

(If additional space is needed, please attach page)

The Prothonotary will not process the complaint, answer, or first responsive pleading in this matter for service until the case information statement (CIS) is filed. The failure to file the CIS and have the pleading processed for service may result in the dismissal of the complaint or may result in the answer or first responsive pleading being stricken.

EXHIBIT 1 – Case Information Sheet

Additional Plaintiffs

Donna Adkins	Amy Greer	Constance Parker
Sandra Allen	Evangeline Hardaway	Catherine Pierce
April Anderson	Lorraine Harmon	Janice Pinder
Winnie Anderson	Annie Haughton	Kamnoosh Popovecz
Nancy Arseneau	Eartha Hendrick	Maylisa Powell
Virginia Ashenbrenner	Dominga Hernandez-Perez	Sherry Prestidge
Kathy Ash-Naylor		Vicki Price
Martha Austin	Margaret Hildebrand	Lisa Rice
Teresa Baldyga	Judith Hill	Candace Roberts
LaShawn Banks	Sandra Holifield	Elizabeth Roberts
Constance Barton	Melba Jackson	Jamie Roberts
Pamela Batcheller	Debra Kaiser	Patricia Salonen
Debra Bealin	Mary Kallio	Felicia Sanders
Veda Bennett	Shanon Kearns	Sherry Sarten
Erica Burney	Julie Koshorek	Mary Schade
Barbara Byers	Michalene Kosinski	Juanita Schleiff
Anita Carr	Nikki Kull	Lisa Screeton
Cynthia Chapo	Michelle Kunnary	Jane Sheehan
Betty Clemons	Dorothy Lawson	Heather Snow
Catherine Cottrell	David Mancini	Gervaise Stepp
Theresa Craig	Patrease Mann	Letitia Summers
Mary Crowley Wakeman	Sally Manuel	Kathy Taylor
Carol Delmonico	Terri Martin	Toni Vanchina
Erin Dunston	Daniela McDonald	Catherine Walker
Glenda Eagleson	Kelly McElroy	Laurie Whalon
Iris Elliott	Allison McInnis	Christina Whiteaker
Evelyn Fanning	Musette Mitchell	Andline Williams
Beatriz Fornells	Tracy Montgomery	Diane Winchoba
Jennifer Gagne	Pamela Mueller	Tina Young
Tonya Gaston	Linda Nichols	Carol Ziman,

Related Cases

Donna Adkins v. GlaxoSmithkline, LLC, Case: N22C-08-034 VLM

Otilio Acevedo V. GlaxoSmithkline, Case: N22C-08-050 VLM

Willie Ard V. GlaxoSmithkline Case: N22C-08-054 VLM

EFiled: Aug 18 2022 11:42PM EDT
Transaction ID 67947542
Case No. N22C-08-173 VLM

SUPERIOR COURT FORM 30

In accordance with Superior Court Civil Rule 5(b)(1)

Form 30. Interrogatories to be answered by a personal injury litigation party.

1. Give the name and present or last-known residential and employment address and telephone number of each eyewitness to the incident which is the subject of the litigation.

To be provided to counsel.

2. Give the name and present or last-known residential and employment address and telephone number of each person who has knowledge of the facts relating to the litigation.

To be provided to counsel.

3. Give the names of all persons who have been interviewed in connection with the above litigation, including the names and present or last-known residential and employment addresses and telephone numbers of the persons who made said interviews and the names and present or last-known residential and employment addresses and telephone numbers of persons who have the original and copies of the interview.

To be provided to counsel.

4. Identify all photographs, diagrams, or other representations made in connection with the matter in litigation, giving the name and present or last-known residential and employment address and telephone number of the person having the original and copies thereof. (In lieu thereof, a copy can be attached.)

To be provided to counsel.

5. Give the name, professional address, and telephone number of all expert witnesses presently retained by the party together with the dates of any written opinions prepared by said expert. If an expert is not presently retained, describe by type the experts whom the party expects to retain in connection with the litigation.

To be provided to counsel.

6. Give a brief description of any insurance policy, including excess coverage, that is or may be applicable to the litigation, including:

a) The name and address of all companies insuring the risk;

_____

b) The policy number(s);

_____

c) The type of insurance;

_____

d) The amounts of primary, secondary, and excess coverage.

_____

7. (Additional interrogatory to be answered by a personal injury litigation plaintiff only) Give the name, professional address, and telephone number of all physicians, chiropractors, psychologists, and physical therapists who have examined or treated you at any time during the ten year period immediately prior to the date of the incident at issue in this litigation.

To be provided to counsel.

EFiled: Aug 18 2022 11:42PM EDT
Transaction ID 67947542
Case No. N22C-08-173 VLM

IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

BARBARA ALLISON, *et., al.*, Plaintiffs, v. GLAXOSMITHKLINE, LLC; PFIZER, INC.; BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.; BOEHRINGER INGELHEIM USA CORPORATION; SANOFI-AVENTIS U.S. LLC; SANOFI U.S. SERVICES, INC.; AND PATHEON MANUFACTURING SERVICES LLC. Defendants.	**SUMMONS** Case No: N22C-08-053 VLM JURY TRIAL OF 12 DEMANDED

SUMMONS

THE STATE OF DELAWARE,
TO THE SHERIFF OF KENT COUNTY :
YOU ARE COMMANDED :

To summon the above-named defendants, so that, within 20 days after service hereof, exclusive of the day of service, defendant shall serve upon Bernard G. Conaway, Esquire, as plaintiffs' counsel, at 1007 North Orange Street, Suite 400, Wilmington, DE 19801, an answer to the complaint (and, if an affidavit of demand has been filed, an affidavit of defense).

To serve upon defendants a copy hereof and of the complaint (and of the affidavit of demand if any has been filed).

Dated: *Colleen Redmond*

Per Deputy

TO THE ABOVE-NAMED DEFENDANT:

In case of your failure, within 20 days after service hereof upon you, exclusive of the day of service, to serve on plaintiffs' attorneys, both named above, an answer to the complaint (and, if an affidavit of demand has been filed, an affidavit of defense), and an answer to the complaint of plaintiff, judgment by default will be rendered against you

for the relief demanded in the complaint (or in the affidavit of demand, if any).

Dated: *Colleen Redmond*

Per Deputy

EFiled: Aug 18 2022 11:42PM EDT
Transaction ID 67947542
Case No. N22C-08-173 VLM

IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

BARBARA ALLISON, *et., al.*, Plaintiffs, v. GLAXOSMITHKLINE, LLC; PFIZER, INC.; BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.; BOEHRINGER INGELHEIM USA CORPORATION; SANOFI-AVENTIS U.S. LLC; SANOFI U.S. SERVICES, INC.; AND PATHEON MANUFACTURING SERVICES LLC. Defendants.	**SUMMONS** Case No: JURY TRIAL OF 12 DEMANDED

SUMMONS

THE STATE OF DELAWARE,
TO THE SHERIFF OF NEW CASTLE COUNTY:
YOU ARE COMMANDED :

To summon the above-named defendants, so that, within 20 days after service hereof, exclusive of the day of service, defendant shall serve upon Bernard G. Conaway, Esquire, as plaintiffs' counsel, at 1007 North Orange Street, Suite 400, Wilmington, DE 19801, an answer to the complaint (and, if an affidavit of demand has been filed, an affidavit of defense).

To serve upon defendants a copy hereof and of the complaint (and of the affidavit of demand if any has been filed).

Dated: *Colleen Redmond*

Per Deputy

TO THE ABOVE-NAMED DEFENDANT:

In case of your failure, within 20 days after service hereof upon you, exclusive of the day of service, to serve on plaintiffs' attorneys, both named above, an answer to the

complaint (and, if an affidavit of demand has been filed, an affidavit of defense), and an answer to the complaint of plaintiff, judgment by default will be rendered against you for the relief demanded in the complaint (or in the affidavit of demand, if any).

Dated: *Colleen Redmond*

Per Deputy

EFiled: Aug 18 2022 11:42PM EDT
Transaction ID 67947542
Case No. N22C-08-173 VLM

IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

BARBARA ALLISON, *et., al.*, Plaintiffs, v. GLAXOSMITHKLINE, LLC; PFIZER, INC.; BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.; BOEHRINGER INGELHEIM USA CORPORATION; SANOFI-AVENTIS U.S. LLC; SANOFI U.S. SERVICES, INC.; AND PATHEON MANUFACTURING SERVICES LLC. Defendants.	Case No: JURY TRIAL OF 12 DEMANDED

PRAECIPE

TO: Prothonotary
New Castle County Court House
500 King Street
Wilmington, DE 19801

PLEASE ISSUE A SUMMONS directing the *Sheriff of New Castle County* to serve the Summons, Complaint, and CIS, pursuant to 10 DEL. C. § 3111, upon the registered agent of each Defendant identified below:

1. **GLAXOSMITHKLINE LLC**
   c/o Corporation Service Company
   251 Little Falls Drive
   New Castle County, Wilmington, DE 19808

2. **SANOFI US SERVICES INC.**
   c/o Corporation Service Company
   251 Little Falls Drive
   New Castle County, Wilmington, DE 19808

3. **SANOFI-AVENTIS U.S. LLC**
   c/o Corporation Service Company
   251 Little Falls Drive
   New Castle County, Wilmington, DE 19808

4. **PFIZER, INC**.
   c/o The Corporation Trust Company
   Corporation Trust Center
   1209 Orange Street
   New Castle County, Wilmington, DE 19801

5. **BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.**
   c/o The Corporation Trust Company
   Corporation Trust Center
   1209 Orange St
   New Castle County, Wilmington, DE 19801

6. **BOEHRINGER INGELHEIM USA CORPORATION**
   c/o The Corporation Trust Company
   Corporation Trust Center
   1209 Orange Street
   New Castle County, Wilmington, DE 19801

FURTHER, PLEASE ISSUE A SUMMONS directing the *Sheriff of Kent County* to serve the Summons, Complaint, and CIS, pursuant to 10 DEL. C. § 3111(a) upon the registered agent of each Defendant identified below:

7. **PATHEON MANUFACTURING SERVICES LLC**
   c/o Capitol Services, Inc.
   108 Lakeland Ave.
   Kent County, Dover, DE 19901

Dated: August 5, 2022

CONAWAY-LEGAL LLC

/s/ Bernard G. Conaway
Bernard G. Conaway, Esquire (DE No: 2856)
1007 North Orange Street, Suite 400
Wilmington, DE 19801
(302) 428-9350 (o)
(844) 364-0137 (f)
bgc@conaway-legal.com

Attorney for the Plaintiffs